Institution: University of Hull

Unit of Assessment: 24 Sport & Exercise Sciences, Leisure & Tourism

Title of case study: Stepping forward: Improving quality of life through better health and mobility for people following lower limb amputation

Period when the underpinning research was undertaken: 2006 to 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:
Professor Natalie Vanicek	Professor of Clinical Biomechanics	09/2004 to 02/2012 and 10/2013 to present
Dr John Perry	Lecturer	07/2015 to 01/2018
Dr Remco Polman	Reader	02/2004 to 05/2008
Professor Lars McNaughton	Professor	01/2003 to 05/2010

Period when the claimed impact occurred: 2013 to 2020

Is this case study continued from a case study submitted in 2014? No

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

Research at the University of Hull (UoH) has: informed British and Dutch national clinical guidelines on the rehabilitation of patients following lower limb amputation (LLA), utilised by 1550 healthcare practitioners; contributed to evidenced-based changes to rehabilitation services for people with a LLA in the UK; established an innovative community-based exercise programme for patients in East Yorkshire and North Lincolnshire and accessible nationally online via the Limbless Association; and demonstrated the benefits of a functional ankle-foot prothesis. These activities have led to better physical, mental and social health and wellbeing for people living with LLA, and an improved quality of life (QoL).

2. Underpinning research (indicative maximum 500 words)

The underpinning research comprises a group of studies led by Natalie Vanicek (Professor of Clinical Biomechanics) at the UoH. This body of research was initiated in 2006 and was aimed at improving mobility and reducing falls for people following LLA, an under-represented group in healthcare research. Vanicek has led pioneering research in two main areas:

Exercise for QoL following LLA

From 2006 to 2010, the research developed a framework for identifying biomechanical factors that distinguished fallers from non-fallers. As a direct result, evidence-based recommendations for falls prevention through structured exercise were established for people with a LLA [3.1-3.2]. The next phase of research (2013 to 2018) was funded by the British Association of Chartered Physiotherapists in Amputee Rehabilitation (BACPAR) and local Hull charity Help for Health. It served to validate and extend those recommendations through the design of a specialised exercise programme for adults with LLA. The findings from the randomised controlled trial (RCT) confirmed many of the recommendations made by Vanicek et al. [3.1-3.2]. A personalised 12-week exercise programme, (delivered in a group setting at UoH, combined with home-based exercise), demonstrated a significant reduction in falls that was long-lasting, persisting at one-year follow-up [3.3]. Moreover, the results indicated that the programme significantly improved walking speed by 0.21 m/s, exceeding the minimum detectable change (of 0.13 m/s) for adults with mobility difficulties [3.3]. This research was also the first to identify that a specifically designed exercise programme significantly improved balance when measured objectively using computerised dynamic posturography, by reducing reliance on visual information and/or by enhancing interpretation from sensory input during stable and unstable balancing conditions [3.4]. **The findings were the first published set of results to evidence the benefits of personalised exercise for falls prevention and better functional performance following LLA.**

Despite the strong evidence for the benefits of exercise, a gap in healthcare service persisted as there were no regional, community-based exercise programmes to address the specific needs of people living with limb loss. In 2018, a pilot study was launched whereby UoH provided people

with a LLA the opportunity to engage in personalised exercise within a community setting. The participants' feedback highlighted the "**life-changing**" experience of exercising within a community setting (e.g. *"The gym has changed how I look at life because it's given me confidence")* [3.5], and this pilot study provided the rationale for establishing the **KEEP MOVING** programme described in section 4 below.

STEPFORWARD: a RCT of a self-aligning prosthetic ankle-foot for older people with LLA

Prosthetics therapies within the NHS are an under-researched area, especially concerning prosthetics provision for older patients with a LLA. Funded by the NIHR (Research for Patient Benefit) programme, this body of research has demonstrated the feasibility of a large-scale trial investigating the effectiveness for patients (and cost-effectiveness for the NHS) of a self-aligning prosthetic ankle-foot compared to a standard ankle-foot [3.6]. The multi-centre RCT was one of few clinical trials in prosthetics therapies conducted in the UK, and recruited patients across England. STEPFORWARD involved a multi-disciplinary group of researchers, healthcare professionals (consultants, prosthetists, physiotherapists) and patients nationally to deliver successfully on a unique area of research. The trial demonstrated high retention and treatment completion rates, and a signal of efficacy for walking ability and QoL outcomes. The STEPFORWARD study has provided a better understanding of patient recruitment and variation between NHS sites for prosthetics therapies - vital to support all further research in this area.

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

3.1 **Vanicek N**, Strike S, **McNaughton L**, **Polman R**. Postural responses to dynamic perturbations in amputee fallers vs. non-fallers: a comparative study with able-bodied subjects. *Arch Phys Med Rehabil* 2009b; 90: 1018-1025. http://dx.doi.org/10.1016/j.apmr.2008.12.024

3.2 **Vanicek N**, Strike S, **McNaughton L**, **Polman R**. Gait patterns in transtibial amputee fallers vs. non-fallers: biomechanical differences during level walking. *Gait Posture* 2009a; 29: 415-420. http://dx.doi.org/ 10.1016/j.gaitpost.2008.10.062

3.3 Schafer ZA, **Perry JL, Vanicek N**. A personalised exercise programme for individuals with lower limb amputation reduces falls and improves gait biomechanics: A block randomised controlled trial. *Gait Posture* 2018; 63: 282-289. https://doi.org/10.1016/j.gaitpost.2018.04.030

3.4 Schafer ZA, **Vanicek N**. A block randomised controlled trial investigating changes in postural control following a personalised 12-week exercise programme for individuals with lower limb amputation. *Gait Posture* 2021; 84: 198-204 https://doi.org/10.1016/j.gaitpost.2020.12.001 (accepted 2 December 2020; available online 9 December 2020.)

3.5 **Vanicek N**. Specialised exercise for individuals with lower limb loss: Reflections from Hull. In International Society for Prosthetics and Orthotics (ISPO UK MS) Annual Scientific Meeting, Southampton, 2018

3.6 Mitchell N, Coleman E, Watson J, Bell K, McDaid C, Barnett C, Twiste M, Jepson F, Salawu A, Harrison D, **Vanicek N**. Self-aligning prosthetic device for older patients with vascular-related amputation: protocol for a randomised feasibility study (the STEPFORWARD study). *BMJ Open* 2019; 9:e032924 http://dx.doi.org/10.1136/bmjopen-2019-032924

Grants (all grant funding was peer-reviewed and competitively awarded)

1. *KEEP MOVING.* To Vanicek (PI) from Ferens Education Trust; July 2020 to July 2021; £2,680
2. *STEPFORWARD: Patient acceptability of a novel prosthetic device: A randomised feasibility study in older patients with vascular-related amputations and multimorbidities.* To Vanicek (Chief Investigator) from National Institute for Health Research (NIHR) Research for Patient Benefit Programme (PB-PG-0816- 20029); April 2018 to March 2020; £248,894
3. *Maximising musculoskeletal function for falls prevention in lower-limb amputees.* To Vanicek (PI) from British Association of Chartered Physiotherapists in Amputee Rehabilitation; April 2015 to March 2018; £3,250
4. *Maximising musculoskeletal function for falls prevention in lower-limb amputees.* To Vanicek (PI) from Help for Health; January 2015 to December 2017; £2,000

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

Changed clinical guidelines and practice (UK and Netherlands) – impacts for practitioners and their patients

In the previous REF period, the earlier research in this body of work informed BACPAR's 2012 2nd edition *Evidence Based Clinical Guidelines for the Physiotherapy Management of Adults with Lower Limb Prostheses*, specifically in respect of the *Prosthetic Rehabilitation Programme* (PRP) [5.1a, p21-22]. That specific guideline received the highest grade A recommendation. In the updated 3rd edition (2020) [5.1b, p7-9], more recent research from UoH was also included - in section 5: *Patient Education*, specifically related to coping strategies following falls, and in section 6: *Discharge, Maintenance and Participation*, contributing to clinical recommendations, with a B grading [5.1b, p12, p14). Both editions (2nd and 3rd) of the BACPAR Guidelines are accredited by the National Institute for Health & Care Excellence (NICE) and inform the practice of all physiotherapists involved in the care of patient with a LLA.

A recent survey of BACPAR members revealed that the PRP section of the 2012 Guidelines continued to be used on a daily to weekly basis by 97% of members during the current REF period [5.2]. In 2017, BACPAR updated the Guidelines based on the latest research evidence [5.3], by conducting a literature search, followed by a Delphi consensus tool to inform the best practice points. An audit tool was also developed to support the continuing professional development that promotes the use of the Guidelines. As well as integrating the findings of the UoH research, Vanicek's expert opinion was sought by BACPAR through her appointment to its Guidelines Update Group (as an Allied Associate Member of BACPAR) from 2018 to 2020 [5.3].

BACPAR's Guidelines Coordinator states [5.3]: "*The work of our members is essential in supporting lower limb amputees to achieve as complete a rehabilitation as possible. BACPAR's key aims include supporting and promoting evidence-based practice and research in amputee and prosthetic rehabilitation… and* ***that update [of the Guidelines] has drawn on the research and expertise of Professor Natalie Vanicek at the University of Hull… BACPAR fully endorses the approaches to coping strategies following falls for people with a lower limb amputation as recommended and validated by Natalie and her colleagues' research****. Having access to this research allows clinicians providing amputee rehabilitation to make service changes where necessary to deliver an effective evidence-based service. We greatly value the benefits these research-based exercise interventions bring to our patients in terms of improved physical and mental health and better balance confidence*".

The revised Clinical Guidelines were due to be published in 2020 but, due to the COVID-19 pandemic (when many members of the Guidelines Update Group were redeployed within the NHS), publication was inevitably delayed. However, the 2012 Guidelines, to which the UoH outputs also contributed [5.1a], have been in continuous use from 1st August 2013 to 31st December 2020, and BACPAR's Guidelines Coordinator confirms the reach of that impact [5.3]: "*We have approximately 250 members across the UK, including physiotherapists, occupational therapists, and prosthetists [and] there are 6,000 new referrals to prosthetics services every year in the UK*".

A survey of BACPAR members about the use of the PRP section of the Guidelines [5.2] showed that:

- 84.4% have used it to support changes to their service.
- 96.9% incorporate the recommendations, when treating patients with a LLA, daily or weekly.
- 87.5% feel it is extremely valuable or very valuable to support the effective rehabilitation of patients with LLA.
- 84.4% feel its recommendations are extremely beneficial or very beneficial to their patients.

As one practitioner commented [5.2] "*As an experienced practitioner they are innate to our practice… For [the] less experienced practitioner they are an excellent starting point in order to give [the] patient [the] best possible care, remind them of the necessities. They are also helpful when discussing service needs etc*."

The reach of the impact on clinical guidelines and practice has been extended to The Netherlands through the use of the underpinning research to inform the Dutch national guidelines on

Amputation and Prosthetics for the Lower Extremities (published November 2020). The President of the International Society for Prosthetics & Orthotics, Netherlands confirms [5.4] that "*research undertaken by Professor Vanicek and her colleagues at the University of Hull has been included in the updated Dutch clinical guidelines on amputation and prosthetics for the lower extremities* [cited in 5.5]… *In developing the new guidelines, we used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach – the most widely adopted tool in healthcare for grading the quality of evidence and making recommendations – and determined that* ***Prof Vanicek's research was one of only eight studies to be included in our revised guidelines****. The Dutch guidelines are the 'go to' resource for health professionals... working on the rehabilitation and recovery of patients after a lower limb amputation. The Society of Rehabilitation Physicians has a membership of 900 medical doctors and ISPO-NL has a membership of 400 healthcare professionals in the Netherlands who will use the revised guidelines to deliver an excellent standard of care to patients…with the most up-to-date knowledge available.* ***More research, like that of Prof Vanicek's, is needed to continue advancements in the field of prosthetics rehabilitation***."

An innovative community-based exercise programme for people with a LLA (East Yorkshire, North Lincolnshire and nationally online) – impacts for consultants and their patients, and for a limb-loss charity and its members

Prior to the underpinning research, there was no facilitated, structured exercise programme in place for people with a LLA. The Hull & East Riding multidisciplinary healthcare team in prosthetics rehabilitation (including physiotherapists, occupational therapists and prosthetists, within the Hull University Teaching Hospitals NHS Trust) treats around 80 new patients with a major LLA from across East Yorkshire and North Lincolnshire each year [5.6]. The lead clinical consultant had long-since recognised the gap in service provision, leading to patients experiencing more sedentary lifestyles and being isolated from other people with limb loss. The findings of the research provided the necessary evidence to establish (working in collaboration with Vanicek) the ***KEEP MOVING*** **(KM)** exercise programme at the Allam Sports Centre, UoH starting in July 2019 [5.6]. Clinicians can now refer patients with a LLA onto the programme. The consultant states [5.6] "*This unique community-based exercise programme… supports our patients in their long-term physical and mental well-being… From a clinical point of view, the benefits for the amputees have included fewer falls, longer walking distances, improved strength and balance.* ***The feedback from participants has been excellent, with some of them referring to its effects as 'life-changing'. It is clear that KEEP MOVING has had a really meaningful impact for the participants and is capable of being offered at a relatively low cost... It should be offered as an integral part of the package of support for all individuals with limb loss to help them regain or maintain their functionality and improve quality of life".***

Interviews with participants on KM [e.g. 5.7] revealed that the community-based exercise programme has benefitted their physical and mental health positively - reducing falls, improving their general fitness, and facilitating a social support group that had been missing locally. One of the participants said [5.7] *"It's been great… I think* ***the big thing is it's a social group of similar people that have got similar sorts of problems****… one of the things you find when this happens [amputation] is you can become a bit cut off and isolated… I was depressed... So, I've now got a social group that I mix with… I've been doing it [KM] for five weeks and… I've rediscovered some muscles I didn't think I had before… So I think my all-round level of fitness has improved... I think one of the big things with this is, is it will cut down the number of falls that you have because it's predominantly your core muscles that we are trying to improve, which affects your balance."*

Another participant commented in a media interview in April 2020 [5.8] that the KM group had "***turned his life around***". He said: "*You can easily become isolated [following an amputation] and I certainly found those first few months particularly tough*", **but attending the KM classes was vital.** "*They have been really great for me.* ***You get to meet so many people who have been going through similar experiences and it's just really helpful to talk. I thought there was little help out there for me****, but…I realised I could also receive more physiotherapy support, which has really helped me progress*." [5.8]

During the COVID-19 pandemic, when the Allam Sports Centre had to close, Vanicek developed a **partnership with the Limbless Association (LA)** which delivered the KM classes online for

patients in East Yorkshire and North Lincolnshire but **also extended the reach of KM's impacts nationwide**. The LA is the UK's leading charity supporting civilians with limb-loss, and it supports people throughout their journey leading up to and after their amputation, including recovery and rehabilitation. The LA's Midland Hub Co-Ordinator offered the KM programme to LA members across the country via *Virtually Speaking* (an online platform for 1,500 members and service users) [5.9]. The Co-ordinator explains: "***The Keep Moving programme fulfils many of this charity's aims*** *such as reducing the feeling of isolation that many amputees experience by enabling people to meet virtually, teaching amputees to do exercises at home safely and comfortably and helping to improve their health and well-being.* ***The Keep Moving programme is unique in the UK, where there is an obvious gap in programmes that design and deliver exercise especially for people with limb-loss****, and it is really valuable to be able to signpost members to it…. We look forward to continuing our partnership with the virtual Keep Moving programme into the future as we've seen the* ***benefits for our members nationally***."

Delivering a more functional prosthesis for older people with a below-knee amputation – impacts for trial participants and practitioners

The STEPFORWARD RCT described in section 2 (April 2018 to March 2020) demonstrated the feasibility of conducting a large-scale trial investigating the effectiveness for patients, and cost-effectiveness for the NHS, of a self-aligning prosthetic ankle-foot. The trial also had clearly demonstrable benefits for the participants. Feedback revealed that a more functional ankle-foot had improved their daily function and QoL in meaningful ways, including reduced pain and enhanced mobility. Feedback included: "*Well, the best thing about it was I could get up and walk about without being in a lot of pain in the foot… you felt the difference as soon as they put the foot on and I stood up and walked. There was just no pressure in the knee, none in the hip and no pain at all…it was a lot better walking. It's more comfortable.* ***It's the best thing that could have happened***" [5.10]. One of the trial partners Portsmouth Hospitals University NHS Trust, and its Amputee Specialist Physiotherapist has confirmed [5.11] "*As specialist physiotherapists,* ***the benefits of the self-aligning ankle-foot were clearly evident in terms of the patients' improved mobility, confidence and balance****. Patients also reported that there were other less visible but equally important benefits of the new prosthetic ankle-foot, like reduced pain and discomfort from wearing a prosthesis daily and generally feeling more confident about moving around their environment.*"

5. Sources to corroborate the impact (indicative maximum of 10 references)
All available as pdfs on request.

5.1 BACPAR Evidence Based Clinical Guidelines for the Physiotherapy Management of Adults with Lower Limb Prostheses 2012 (5.1a) and 2020 (5.1b)

5.2 Results of survey of BACPAR members

5.3 Testimonial from Guidelines Coordinator, British Association of Chartered Physiotherapists in Amputee Rehabilitation (BACPAR)

5.4 Testimonial from President of International Society for Prosthetics & Orthotics, Netherlands

5.5 Dutch guidelines on amputation and prosthetics for the lower extremities 2020 (written in Dutch – not available in English)

5.6 Testimonial from Consultant in Rehabilitation, Hull University Teaching Hospital NHS Trust

5.7 Transcript of BBC radio interview with *Keep Moving* participant 1

5.8 Hull Daily Mail article about *Keep Moving* participant 2

5.9 Testimonial from Chief Executive Officer and *Support & Connect* Midland Hub Co-Ordinator, Limbless Association

5.10 Feedback from STEPFORWARD participants

5.11 Testimonial from Amputee Specialist Physiotherapist, Portsmouth Hospitals University NHS Trust