

Institution: Bangor University, 10007857		
Unit of Assessment: UoA 3 - Allied Health Professions, Dentistry, Nursing and Pharmacy		
Title of case study: Saving limbs: North Wales clinical-care model for patients at risk of amputation has national and international impact.		
Period when the underpinning research was undertaken: 2006 - 31 December 2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s): Dean Williams Chris Whitaker	Role(s) (e.g. job title): Professor of Surgery (Teaching & Scholarship) Research Fellow and Principal Statistician North Wales	Period(s) employed by submitting HEI: January 2006 - September 2020 January 1981 - September 2014
Period when the claimed impact occurred: 1 August 2013 - 31 July 2020		
Is this case study continued from a case study submitted in 2014? N		
1. Summary of the impact		
<p>Under the leadership of Bangor University's Professor Dean Williams, the vascular surgery department at Ysbyty Gwynedd Hospital introduced a research-verified novel approach to the management of patient-groups at risk of lower-limb amputation (e.g. diabetics, rheumatoid arthritis sufferers and intravenous drug users). This rapid-access multidisciplinary clinical-care model led to a significant and sustained decrease in lower-limb amputation rate (over 95% and over 80% reduction, respectively, for diabetic and non-diabetic patients; regional population level). Wider impact was demonstrated by the inclusion of key research citations in national (NICE Diabetic foot guidelines 2015) and international guidelines. The Bangor-developed clinical-care model has informed clinical best-practice of vascular surgeons nationally and internationally. Williams also plays a critical advisory role for NHS Digital, auditing UK diabetic foot-care for NICE guideline compliance.</p>		
2. Underpinning research		
Context		
<p>Due to an ageing population and an increase in obesity, the incidence of type 2 diabetes is predicted to rise to 5,000,000 in the UK and 505,000,000 worldwide by 2025. Diabetic foot disease, a complication of diabetes, is a common cause of hospital admissions in the UK, representing a huge financial burden to both the NHS and health systems throughout the developed world. Unfortunately, diabetic foot disease can lead to lower-limb amputations, with a lifetime amputation rate 10 to 30 times higher than that within the general population. In addition, certain non-diabetic patient groups (e.g. rheumatoid arthritis sufferers and intravenous drug users) are at particular risk of lower-limb amputations.</p>		
<p>Dean Williams is Professor of Surgery at Bangor University and a vascular surgeon in the vascular surgery department of Ysbyty Gwynedd hospital (Bangor). Under his leadership, two complementary novel clinical-care models associated with improved outcomes for patients with limb threatening diseases, the "Diabetic foot service" and the "Limb salvage unit", were developed, implemented and researched. The prospective collection and review of clinical outcome data (e.g.</p>		

lower-limb amputation rate) illustrate the importance of this evidence-based approach to clinical care.

Diabetic foot service

In 2006, the innovative, integrated, multidisciplinary diabetic foot service was set up in the vascular surgery department of Ysbyty Gwynedd hospital, Bangor. This service provided a dedicated rapid access pathway for patients with diabetic foot emergencies, augmenting the service already provided locally by allowing rapid, accurate assessment and commencement of treatment of patients requiring emergency treatment under a vascular surgeon. Under the previous care model (in line with NICE guidelines of 2006), referral to a vascular surgeon only occurred when peripheral arterial disease was suspected, leading to late-stage referral in clinical practice.

Bangor-led research into the effectiveness of the new diabetic foot service (published in 2012 with statistical analysis by Bangor's Chris Whitaker) [3.1], compared numeric data on patient groups with lower-limb disease associated with diabetes, collected prospectively during the first four years of the service (2006 to 2009), with data retrieved from the two-year period prior to the commencement of the service, on the main outcome of major lower-limb amputation (above the ankle). Statistical analysis demonstrated a decrease of over 95% for major amputations associated with diabetes (peak of 25/10,000 prior to 2006 *versus* 1/10,000 by 2009) as a result of this rapid-access pathway model [3.1]. Further research-evidence (published in 2017) [3.2] clearly illustrated the continued success of this service by the maintenance of this lower amputation rate.

Limb salvage unit

The limb salvage unit was set up in tandem with the diabetic foot service in 2006, following a similar rapid-response multi-disciplinary approach but expanding the reach to non-diabetic patients. Data was collected prospectively on lower-limb amputations in this group over a ten-year period (2006 to 2015) and retrospectively retrieved for 2004 to 2005 (prior to unit commencement). Sustained reductions in major lower-limb amputation rates of over 80% were recorded for the non-diabetic population (15/100,000 person-years prior to 2006 *versus* 2/100,000 between 2006 and 2015) as a result of the limb salvage unit [3.3].

A particular group of patients, those with connective tissue disorders (e.g. rheumatoid arthritis), are prone to persistent leg-ulcers that are difficult to manage and often result in long-term reduction in quality of life including amputation of lower-limbs. Novel research led by Williams, conducted alongside clinical-practice in the limb salvage unit (from 2006 onwards), suggested that clinical-care of leg-ulcers in this patient group should focus on aggressive treatment of underlying inflammation and improving patient nutrition [3.4], in order to minimise future lower-limb amputations. Another group of non-diabetic patients, intravenous drug users presenting with bleeding and/or ischaemia (restriction of blood supply to tissues) of the lower limbs, are also at high risk of lower-limb loss. In 2017 Williams conducted research into a novel technique to control bleeding, endovascular coiling to induce thrombosis in arteries, finding this reduced or removed the need for lower-limb amputation in this patient group [3.5]. Recent Bangor-led research has focused on axillofemoral bypass using vein grafts to save limbs in patients at high-risk of complications including infection [3.6].

3. References to the research

- 3.1 **Williams, D. T.**, Majeed, M. U., Shingler, G., Akbar, M. J., Adamson, D. G. and **Whitaker, C. J.** (2012) A diabetic foot service established by a department of vascular surgery: An observational study. *Annals of Vascular Surgery*, **26**(5), 700-706. [DOI](#) (Peer-reviewed journal article)
- 3.2 **Williams, D. T.**, Powell-Chandler, A. and Griffiths, O. G. (2017) A diabetic foot service in a Department of Vascular Surgery. Updates and consensus in Vascular surgery. In Greenhalgh, R. M., MA, MD, MChir, FRCS (ed.) *Vascular and Endovascular Consensus Update 2017*. Biba Publishing.
- 3.3 **Williams, D. T.**, Powell-Chandler, A., Qureshi, Q., Zaidi, A. and **Whitaker, C. J.** (2018) Improved limb salvage for patients with vascular disease and tissue loss associated with new model of provision targeted at the diabetic foot. *Diabetes Research and Clinical Practice*, **135**, 50-

57. [DOI](#) (Peer-reviewed journal article)

3.4 Harries, R. L., Ahmed, M., **Whitaker, C. J.**, Majeed, M. U. and **Williams, D. T.** (2014) The influence of connective tissue disease in the management of lower limb ischemia. *Annals of Vascular Surgery*, **28**(5), 1139-1142. [DOI](#) (Peer-reviewed journal article)

3.5 Eley, C. L. and **Williams, D. T.** (2019) Coil embolization of femoral pseudoaneurysms in intravenous drug users: an additional treatment modality. *Annals of Vascular Surgery*, **58**, 317-325. [DOI](#) (Peer-reviewed journal article)

3.6 **Williams, D. T.**, Bandyopadhyay, S. K., Morais, A. F. A. B. and Povey, H. G. (2020) Axillofemoral bypass using vein grafts for complicated peripheral arterial disease. *Journal of Vascular Medicine and Surgery*, **8**(5) [LINK](#) (Peer-reviewed journal article)

4. Details of the impact

Regional impact

The diabetic foot service, introduced by Professor Dean Williams and validated by Bangor-led research, demonstrated a decrease of over 95% for major amputations associated with diabetes as a result of the implementation of this rapid-access clinical-care model (by the vascular surgery department of Ysbyty Gwynedd hospital). This service has had major clinical outcomes, with the regional Betsi Cadwaladr University Health Board (BCUHB) recording the lowest number of diabetic major amputations in Wales over a 6-year period (between 2009 and 2014) **[5.1]**. In 2015, BCUHB supported expansion of the diabetic foot service to the entire population of North East Wales, thus this 24/7 rapid-access emergency service then covered a population totalling over 680,000 people.

Informing national and international guidelines

Bangor-led research on the impact of the diabetic foot service on lower-limb amputation rates informed the 2015 National Institute for Health and Care Excellence (NICE) guidelines on Diabetic foot problems: prevention and management **[5.2, 5.3]**. These updated guidelines cite key Bangor research referring to the diabetic foot service clinical-care model, stating: i) “*multidisciplinary foot care services should be led by ... (or include) ... a specialist in vascular surgery*” (i.e. the core team structure proposed by Williams); and ii) recommend that “*if a person has a limb or life-threatening foot problem, refer them immediately to acute services and inform the multidisciplinary foot care service*” (i.e. the rapid-access clinical-care model proposed by Williams).

All UK healthcare providers are required to implement NICE guidelines, with adherence monitored by NHS Digital. As a result, the Bangor-developed diabetic foot service clinical-care model has been adopted by the majority of UK healthcare providers (on the basis of the 2015 NICE guidelines update), leading to enhanced care for the patient population with diabetes-related lower limb complications. Indeed, the closer a diabetic foot service adheres to 10 key aspects (including multidisciplinary care and access to vascular expertise as recommended by Bangor-research and now included in the NICE guidelines), the better patient outcomes are, including lower amputation rates **[5.4]**.

Bangor-led research on the Diabetic foot service rapid-access clinical-care model has also informed the recent Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischaemia (2019) **[5.5]**, specifically the section on creation of centres of excellence for amputation prevention, with our research (1 of only 2 UK sources) cited as “*The United Kingdom has also seen reduced amputations secondary to better-organized diabetic foot care with specialised clinics that follow multidisciplinary care pathways and protocols*”.

Informing and Monitoring Clinical Practice

Bangor’s vascular unit has become internationally recognised for the expert management of lower limb wounds and vascular disease as led by Williams. Vascular surgeons from the USA (DeBakey Heart and Vascular Centre in Houston, Texas) and Europe visited the vascular unit to learn from Williams’ research-validated approach via an overseas fellowship scheme (2016 to 2017) **[5.6]**. One of the vascular surgeons who participated in this scheme has subsequently developed a multi-disciplinary out-patient service in line with Williams’ limb salvage service at the DeBakey

Heart and Vascular Centre (a specialist hospital for veterans). Williams also shares best-practice with international audiences of vascular clinicians, giving invited keynote presentations at the Charing Cross International Vascular Symposium (2017), the Annual Danish Vascular Meeting (2018) and chairing a session on diabetic foot management at the Diabetes UK Annual Conference (2018).

Williams was invited to join the Advisory committee to the National Diabetic Footcare Audit in 2017 as the only vascular surgeon providing expertise specifically on diabetic foot. This audit forms part of NHS Digital that measures the quality of diabetes foot care against national standards set by NICE, and monitors and publishes the performance of all health trusts and boards in the UK set against the NICE guidelines [5.7]. Williams' role here in scrutinising submitted data is critical in understanding diabetic foot care compliance levels.

5. Sources to corroborate the impact

5.1 NHS Wales Informatics Service (Information and Statistics) 2015 Number of amputation operations for patients with diabetes (2009 to 2014) by regional health board. Demonstrates amputation reduction for Betsi Cadwaladr University Health Board (BCUHB) based on Bangor-led clinical-care model. Publicly available by request from pdit.requests@wales.nhs.uk., excel spreadsheet request number 27467, Total Amputation Comparison tab (Bangor University has a requested copy on file).

5.2 National Institute for Health and Care Excellence (August 2015) Diabetic foot problems: prevention and management **NICE guideline (NG19)**. NG19 1.2.3 (p6) provides guideline on the composition of foot protection services and multidisciplinary foot care services. NG19 1.4.1 (p11) provides guideline on indicators for referral to specialist services.

<https://www.nice.org.uk/guidance/ng19/resources/diabetic-foot-problems-prevention-and-management-pdf-1837279828933> (both guidelines directly evidenced by Bangor-led research, see [5.3]).

5.3 National Institute for Health and Care Excellence (August 2015) Diabetic foot problems: prevention and management of foot problems in people with diabetes, **Clinical Guidelines** cite Bangor-led research: NICE guideline NG19 1.2.3 is evidenced by Clinical guideline 4.2, Evidence review 4.2.2 with [3.1] 1 of only 8 research-papers included in final review (p41, line 33). NICE guideline NG19 1.4.1 evidenced by Clinical guideline 4.14, Evidence review 4.14.2, with [3.1] 1 of only 18 studies included in final review (p220 line 16).

<https://www.nice.org.uk/guidance/NG19/documents/diabetic-foot-problems-draft-guideline2>.

5.4 Open-access Diabetes UK publication for clinicians (2018) diabetic foot service adherence to 10 key aspects (including multidisciplinary care and access to vascular expertise as proposed by Williams and cited in the publication via the NICE NG19 guidelines [5.2]) is associated with better patient-outcomes: Paisey, R.B., Abbott, A., Levenson, R., Harrington, A., Browne, D., Moore, J., Bamford, M. and Roe M. on behalf of the South-West Cardiovascular Strategic Clinical Network peer diabetic foot service review team (2018) Diabetes-related major lower limb amputation incidence is strongly related to diabetic foot service provision and improves with enhancement of services: peer review of the South-West of England. *Diabetic Medicine* 35(1), pp53-62. <https://onlinelibrary.wiley.com/doi/10.1111/dme.13512>

5.5 Global guidelines informed by Bangor-led research (2019) with the section on creation of centres of excellence for amputation prevention citing Bangor-led research [3.3] (pS84) in: Conte, M.S., Bradbury, A.W., et al. (2019) Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia. *European Journal of Vascular and Endovascular Surgery*, 58(1), Supplement ppS1-S109.e33 ISSN 1078-5884 <https://doi.org/10.1016/j.ejvs.2019.05.006>

5.6 Testimonial from Vascular Surgeon USA (participant in impact delivery) who completed an overseas fellowship at Bangor's vascular unit and details how he envisages setting up a multi-disciplinary out-patient service based on the Bangor clinical-care model at Michael E. DeBakey VA Medical Center (Baylor College of Medicine), Houston, Texas, USA.

5.7 National Diabetes Foot Care Audit (NDFAThird Annual Report, NHS Digital (2018) lists Dean Williams as member of NDFAT advisory group (p95)

<https://www.hqip.org.uk/wp-content/uploads/2018/03/National-Diabetes-Foot-Care-Audit-2014-2017.pdf>

