

Mind the Gap: Disparity Between Research Funding and Costs of Care for Diabetic Foot Ulcers

Diabetic foot ulceration (DFU) is a serious and prevalent complication of diabetes, ultimately affecting some 25% of those living with the disease (1). DFUs have a consistently negative impact on quality of life and productivity as diabetic patients report stigma, social isolation, unemployment, and depression (2–5). Patients with DFUs also have morbidity and mortality rates equivalent to aggressive forms of cancer (2). These ulcers remain an important risk factor for lower-extremity amputation as up to 85% of amputations are preceded by foot ulcers (6). It should therefore come as no surprise that some 33% of the \$116 billion in direct costs generated by the treatment of diabetes and its complications was linked to the treatment of foot ulcers (7). Another study has suggested that 25–50% of the costs related to inpatient diabetes care may be directly related to DFUs (2).

National standards have been developed for DFU prevention and care (8–10). Given the high prevalence, severity, costs, and morbidity of diabetic foot complications, one would expect that federal funding for DFU research would be proportionate to its public health impact. The National Institutes of Health (NIH) is the major source of federal funding for medical research in the U.S. We therefore examined NIH funding for both diabetes and DFUs using the NIH Research Portfolio Online Reporting Tools (RePORT) from 2002 to 2011 (11). We also examined differences in the number of peer-reviewed publications (using PubMed at www.ncbi.nlm.nih.gov) on both diabetes and diabetic foot ulcers between the years 1980–2010. The search terms included “diabetes,” “diabetic foot ulcers” and the following search string: [diabetic AND (foot OR feet OR toes) AND (wound OR ulcer)]. We used a similar strategy to that of our colleagues Meador et al. (12) and Sen et al. (13), who evaluated disparities between epilepsy research and wound healing.

The number of peer-reviewed DFU publications increased 78% between the

periods of 1980–1989 to 2000–2009. This was similar to the number of total diabetes publications, which increased 72% over the same period (Table 1). The similarities, however, appear to end there. We identified 22,531 NIH-funded projects in diabetes between 2002–2011. Remarkably, of these, only 33 (0.15%) were specific to DFUs. Likewise, these 22,531 NIH-funded projects yielded \$7,161,363,871 in overall diabetes funding, and of this, only \$11,851,468 (0.17%) was specific to DFUs. Thus, a 604-fold difference exists between overall diabetes funding and that allocated to DFUs. These data are outlined in Fig. 1.

As DFUs are prevalent and have a negative impact on the quality of life of patients with diabetes, it would stand to reason that U.S. federal funding specifically for DFUs would be proportionate with this burden. Unfortunately, this yawning gap in funding (and commensurate development of a culture of subspecialty research) stands in stark contrast to the outsized influence of DFUs on resource utilization within diabetes care.

This disparity does not appear to be isolated to one developed nation. Indeed, in the U.K., 89 out of 402 diabetes-related grant applications received by Diabetes UK were funded between 2010 and 2011 (direct request for information, Diabetes UK, 2012). Further, of these 402 U.K. grant applications, only 15 were specific to the diabetic foot. Of these, only one grant application specific to the diabetic foot was funded, accounting for a mere 1.7% of the total Diabetes UK funding during that time period.

Over the past generation, the number of peer-reviewed publications on DFUs has increased fivefold (Table 1). These data are similar to those reported by Boulton (6), who reported that 2.7% of all diabetes publications listed on PubMed were specific to the diabetic foot from 1998 to 2004 compared with 0.7% during the 1980–1998 time period, yielding a fourfold increase. This increase tracks well with the interest level

of clinician-scientists treating the disease.

Why, then, is the gap between the impact of DFUs on the diabetic condition and DFU funding so expansive? Chronic wounds, as a whole, affect nearly 6.5 million patients in the U.S. alone, accounting for approximately \$25 billion in expenditures (13). One could postulate that grants submitted to the NIH on diabetic foot disease were of poor quality and therefore the majority were not funded: This explanation, however, appears to be unlikely as the number of original publications on diabetic foot disease in the peer-reviewed literature has substantially increased in recent years with many articles appearing in high-impact factor journals. An alternative explanation—and a more pragmatic one—might be that mentors specializing in diabetes are advising young physician-scientists against pursuing DFU research because of a lack of opportunity for funding and career advancement. Clearly, the gap between prevalence and funding could have serious consequences for future patient care and research.

It is worth reemphasizing that DFUs are a frequent and costly complication of diabetes. The cumulative lifetime incidence of foot ulcers in diabetic patients may be as high as 25% (14). According to estimates, nearly \$9,000,000,000 were spent on DFU treatment in 2001 alone (13). Between 2005 and 2007, the total incidence of diabetes increased 13.5% (13). From a worldwide perspective, as we face an increasing incidence of type 1 diabetes and an epidemic of type 2 diabetes, the prevalence of diabetic foot ulcers will only rise. The cost of care of people with diabetic foot ulcers is 5.4 times higher in the year after the first ulcer episode than the cost of care of people with diabetes without foot ulcers (10).

Neuropathy and ischemia are the primary underlying risk factors for DFU development (15). Patients with DFUs and concomitant ischemic and neuroischemic disease have worse outcomes.

Table 1—Comparison of peer-reviewed publications on diabetes vs. DFUs

Years	Diabetic foot publications (n)	Diabetes publications (n)	Diabetic foot vs. diabetes publications (%)
1980–1989	254	48,770	0.52
1990–1999	543	82,290	0.66
2000–2009	1,200	174,892	0.69
Total	1,997	305,952	0.65

Indeed, amputation and mortality rates are higher in patients with ischemic and neuroischemic ulcers than in patients with neuropathic ulcers (7,16). Patients with ischemic ulcers also show a higher rate of recurrence, nearly twice as many amputations, and inferior maintenance of ambulation and independence than patients with neuropathic foot ulcers (17). The prevalence of neuroischemic DFUs has been rising since the 1990s from approximately 33% of patients to where it now appears to be the most common etiology of foot ulcers (compared with purely neuropathic wounds) (18,19). Remarkably, no U.S. Food and Drug Administration–approved products or

medical devices for patients with neuroischemic diabetic foot ulcers are currently available as these patients are frequently excluded from clinical study programs.

As we highlight in this article, there is a lack of federally and not for profit–funded research directed toward diabetic foot ulcers. This funding gap is disproportionately large in comparison with the public health impact of this sequela. As a diabetes-related extremity amputation is now performed every 20 s (20), we see a clear and present medical and fiscal calamity. We must mind this gap as a locomotive of lower-extremity complications is approaching our station and is anything but stationary.

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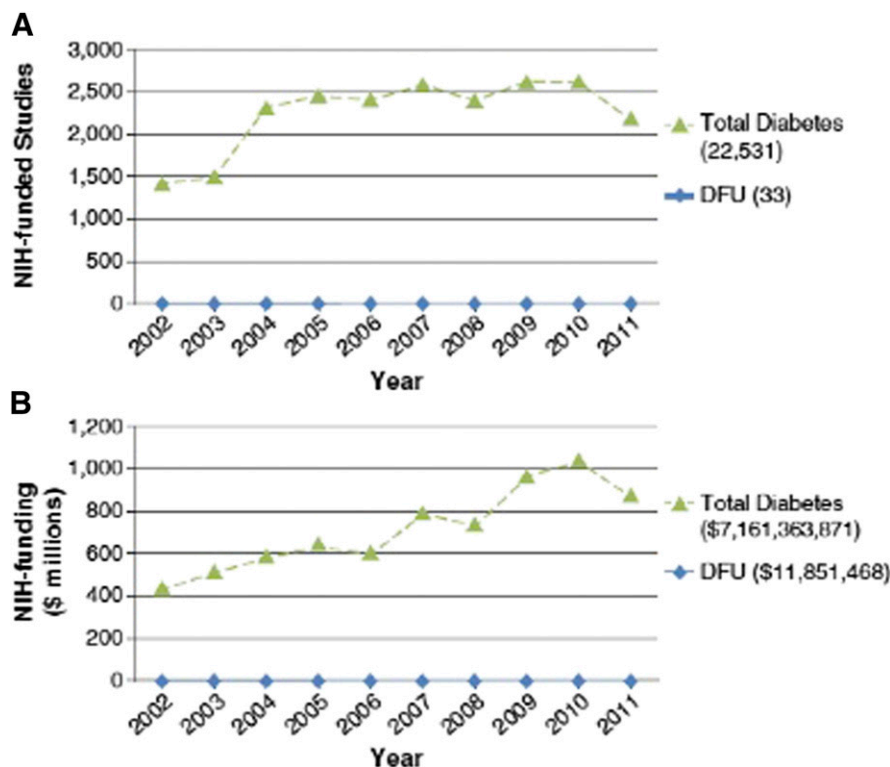


Figure 1—Comparison of NIH funding for diabetes and DFUs between 2002 and 2011. A: Total number of NIH-funded studies per year for diabetes, diabetic neuropathy, and DFUs. Total number of studies in each group is shown in parentheses. The proportion of diabetes funding allocated to DFUs as a function of total NIH diabetes studies is 0.0015. B: Total NIH funding (in millions) allocated per year for diabetes and DFUs. Sum total for each category between 2002 and 2001 is shown in parentheses. The proportion of diabetes funding allocated to DFUs as a function of total NIH diabetes funding is 0.0017.

