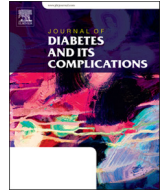




Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



## Strategies to reduce severe diabetic foot infections and complications during epidemics (STRIDE)☆

Brian M. Schmidt\*, Michael E. Munson, Gary M. Rothenberg, Crystal M. Holmes, Rodica Pop-Busui

Michigan Medicine, Department of Internal Medicine, Division of Metabolism, Endocrinology, and Diabetes, Domino's Farms (Lobby C, Suite 1300) 24 Frank Lloyd Wright Drive, Ann Arbor, MI 48106, United States of America

### ARTICLE INFO

#### Article history:

Received 8 July 2020

Received in revised form 21 July 2020

Accepted 21 July 2020

Available online 28 July 2020

#### Keywords:

Diabetic foot ulcer  
Amputation  
Diabetic complications  
Pandemic  
COVID-19  
Triage

### ABSTRACT

**Aims:** Patients with diabetes, including those with foot complications, are at highest risk for severe outcomes during the COVID-19 pandemic. Diabetic foot ulcers (DFU) present additional challenges given their superimposed risk for severe infections and amputations. The main objectives were to develop a triage algorithm to effectively risk-stratify all DFUs for potential complications, complying with social distancing regulations, preserving personal protective equipment, and to assess feasibility of virtual care for DFU.

**Methods:** Longitudinal study during the COVID-19 pandemic performed at a large tertiary institution evaluating the effectiveness of a targeted triage protocol developed using a combined approach of virtual care, electronic medical record data mining, and tracing for rapid risk stratification to derive optimal care delivery methods. 2868 patients with diabetes at risk for foot complications within last 12 months were included and rates of encounters, hospitalizations, and minor amputations were compared to one year prior.

**Results:** The STRIDE protocol was implemented in 1-week and eventually included 2600 patients (90.7%) demonstrating effective triage. During normal operations, 40% (938 of 2345) of all visits were due to DFUs and none were performed virtually. After implementation, 98% face-to-face visits were due to DFU, and virtual visits increased by 21,900%. This risk stratified approach led to similar low rates of DFU-related-hospitalization and minor amputation rates 20% versus 24% ( $p > 0.05$ ) during and prior the pandemic, respectively.

**Conclusions:** Implementation of STRIDE protocol was effective to risk-stratify and triage all patients with diabetic foot complications preventing increase in hospitalization and amputations while promoting both social and physical distancing.

© 2020 Elsevier Inc. All rights reserved.

### 1. Introduction

Diabetic foot ulcers (DFU) remain one of the most common complications of diabetes and are the leading cause of lower extremity amputation with every sixth individual having an early demise as a result.<sup>1–3</sup> Five-year mortality after DFU occurrence is 40%,<sup>4</sup> 10-fold higher than non-diabetic cohorts.<sup>5</sup> Forty percent of DFU recur within one-year following closure adding additional risk to this population.<sup>6</sup> New evidence asserts a recent surge in major lower extremity amputations in diabetic patients despite the previous decades of decline.<sup>7</sup> In spite of these grim facts, it has been established that multidisciplinary team management may reduce the rate of major amputation by more than 50% resulting in improved quality of life and life expectancy for these patients.<sup>8–10</sup>

The rapid explosion of the COVID-19 pandemic has required a sudden shift in best care practices for health care providers and institutions requiring new plans of unprecedented complexity.<sup>11,12</sup> The pandemic still rages and in the United States alone, there have been 2.89 million confirmed cases with daily new cases now reaching 50,000.<sup>13</sup> Patients with diabetes are among the most vulnerable categories for severe COVID-19 related outcomes and are predominantly affected by this change.<sup>14,15</sup> Their vulnerability is attributed to a combination of factors including a higher burden of concurrent comorbidities, chronic inflammation, and presence of diabetes vascular complications.<sup>16–21</sup>

Particularly, patients with diabetes and foot complications including DFU, who normally require frequent care and debridement during face-to-face visits were severely impacted by restrictions implemented to protect these most vulnerable patients from unnecessary exposure, ensure social distancing and curb the spread of COVID-19, and preserve personal protective equipment (PPEs). Thus, the traditional outpatient model focused on regular monitoring and aggressive identification of precursors of morbidity, had to be replaced by untested practices of using telemedicine and patients' self-reporting to risk stratify. Such a rapid devolution of care if not done correctly, may lead to limb

☆ Declaration of competing interest: No potential conflicts of interest relevant to this article were reported.

\* Corresponding author at: University of Michigan Medical School, Department of Internal Medicine, Division of Metabolism, Endocrinology, and Diabetes, 24 Frank Lloyd Wright Drive, Lobby C, Ann Arbor, MI 48106, United States of America.

E-mail address: [Bmcs@med.umich.edu](mailto:Bmcs@med.umich.edu) (B.M. Schmidt).

threatening infections requiring hospitalizations and major amputations, thus placing both additional burden on overstretched health care systems during the ongoing crisis, and resulting in severe patients' related outcomes.

Therefore, the development and implementation of effective care protocols to identify the most at-risk patients and protect them from unnecessary hospitalization and COVID-19 exposure is urgently needed, particularly given the second waves of the pandemic emerging in the USA and other countries.<sup>13</sup>

The COVID-19 pandemic has brought virtual care technologies to the forefront, given the important and ongoing progress made in this field. These technologies provide the initial necessary care while protecting vulnerable individuals and preventing spread of disease, given physical distance. Traditional DFU care requires face-to-face contact for procedures (debridement), although virtual care technologies may offer applicable opportunities for these patients as well. However, there has never been widespread implementation of telemedicine in DFU management and the short and long-term outcomes for diabetic foot salvage are unknown.

Here we discuss a novel and highly effective stepwise strategy developed and implemented by the Michigan Medicine Podiatry Diabetes team to triage and deliver the most appropriate care for all patients with diabetes and foot complications. Our team was well situated to leverage a robust infrastructure and highly skilled clinical and translational research team to generate a functional platform that employs virtual care technologies and a novel adaptive protocol to effectively deliver the necessary care to prevent amputation and death (Fig. 1) that was developed in only 1 week.

**2. Subjects, materials, methods**

This is a longitudinal study during the COVID-19 pandemic performed at a large tertiary institution providing care to approximately

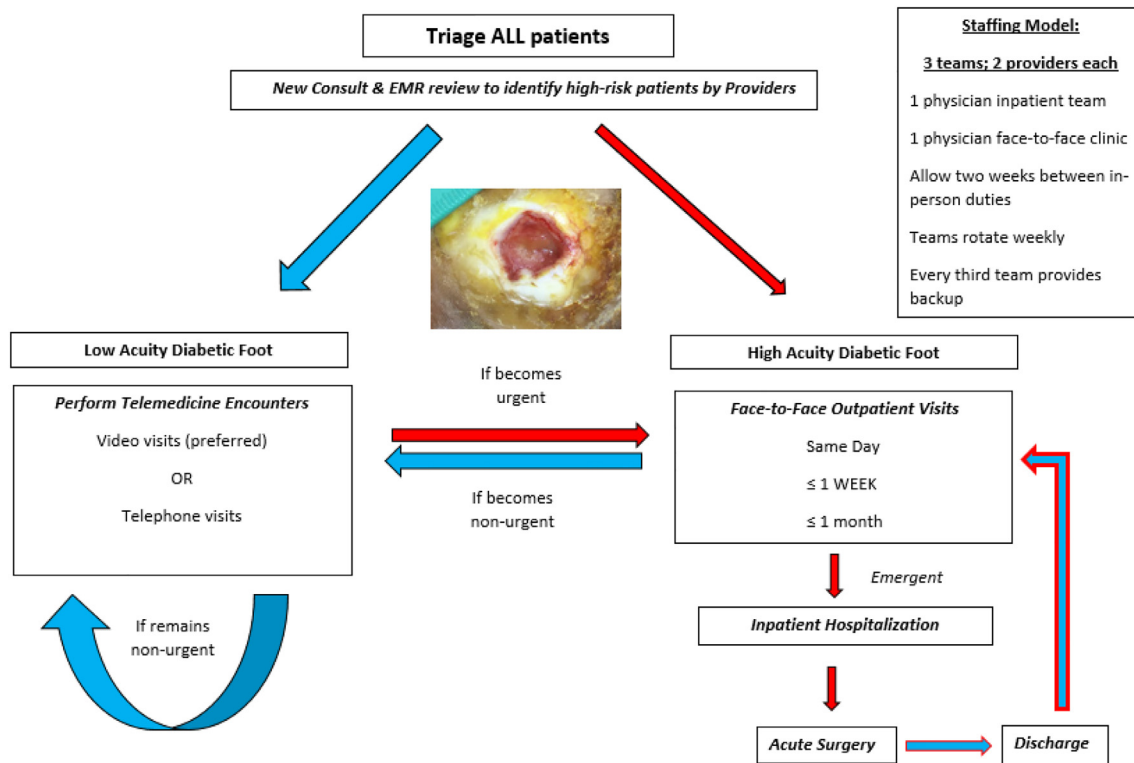
2868 patients with diabetes mellitus and a foot complication within the last 12 months. Electronic medical record (EMR) deep data mining was used to identify all these patients and construct a risk stratification algorithm for each patient as part of STRIDE protocol implemented in first week of March 2020 as described below. Data tracing was then immediately implemented for all patients who received any type of care (virtual either video or telephone, outpatient, inpatient) between March 2020 to end of May 2020.

STRIDE protocol was designed to rapidly evaluate all patients with diabetic foot conditions and identify those with DFU and highest risks, and deliver a risk-stratified care targeted at preventing life threatening complications associated with COVID-19 and end-stage diabetic foot complications. This protocol was also designed to avoid additional unnecessary burden on inpatient care in situations of crisis and protect the susceptible population against worse outcomes. The STRIDE protocol was expeditiously developed by our team in anticipation of an unprecedented increased demand on our inpatient and outpatient services and resources associated with the COVID-19 outbreak. The Michigan Medicine Podiatry Diabetes team fully implemented and integrated this protocol that included several defined steps within one week.

*2.1. Optimal triage algorithm*

The triage includes all staff; primarily physicians and nurses. The goal was to generate an internal list identifying all at-risk patients with DFU and with potential DFU complications.

In phase one, multiple EMR tools were leveraged to target electronic chart screening for outcomes of interest such as lower extremity or foot infections, ischemia, peripheral neuropathy, Charcot Neuroarthropathy, fractures, post-operative status, other comorbidities (advanced stages of retinopathy and vision loss, severe chronic kidney diseases) and socioeconomic status. A risk assessment model was computed and all



**Fig. 1.** Strategies to reduce severe diabetic foot infections during epidemics (STRIDE-DFC) protocol. Figure depicts STRIDE triage protocol to risk-stratify patients with diabetic foot concerns. The process involves triaging ALL patients into low acuity and high acuity concerns. Low acuity patients are managed primarily via telemedicine and triaged to face to face encounters if urgent. Blue arrow indicates lower acuity and red arrows indicate high acuity concerns. Arrow width is associated with volume.

patients were stratified by their risk level. High risk patients included those with new or chronic DFU, infection, or ischemia as defined by guidelines from the Infectious Disease Society of America (IDSA),<sup>22</sup> the International Working Group on Diabetic Foot (IWGDF),<sup>23</sup> and Society of Vascular Surgery guidelines<sup>24</sup>; medium risk patients included those with pre-ulcerative skin lesions and foot deformity; and low-risk included patients with diabetes who were enrolled in our preventative foot clinic. Lists were then generated to provide the team with follow-up options following previously published guidelines.<sup>22,24,25</sup>

The second phase promoted both physical and social distancing by creation of multiple “foot action teams”. A single provider was assigned inpatient duties and one other assigned face-to-face outpatient visits. The remaining teams performed telemedicine duties to maintain contact and provide preventive care for those with lower risk DFU. Rotation of the teams occur weekly with a period of self-isolation built into scheduling following in-person interactions. Physician and staffing back up is provided via a three team tiered system, to allow for a two-week “rest” period, primarily to monitor for symptoms per institutional guidelines, after face-to-face patient contact.

Finally, if the video consulting team identified an acute situation or if clinical deterioration was appreciated, the providers referred directly to the in-person teams, based on the individual level of risk for a specific case for the most appropriate management.

If triaged to the in-person clinic, DFU standard of care practices occurred alongside assessment for infection and ischemia as above. As a result of our outpatient physical presence, providers can continue to service this vulnerable population and address other acute concerns, as needed.

If a limb-threatening emergency is identified, and patients require transfer to hospital and/or surgical intervention, appropriate team members are promptly notified so logistic planning can begin. If COVID-19 cannot be ruled out, as is the case of septic patients from a diabetic foot infection, all necessary teams are notified for coordination of care and appropriate isolation.

## 2.2. Statistical analysis

Data extracted included counts of each type of encounter (virtual, outpatient, inpatient), related to diabetic foot complications including DFU or not, as well as the absolute counts of minor lower extremity amputations, defined as loss of part of the foot, and hospitalizations for severe infections or major amputations. The data was then compared to a historic cohort from the year prior during the same time to assess trends in care using student *t*-testing and proportionality testing. All statistical analysis was completed using SPSS statistical software, version 22 (SPSS Inc. Chicago, IL). Statistical significance was set at the 5% level ( $p \leq 0.05$ ).

## 3. Results

During the COVID-19 pandemic, location of care was drastically altered for patients with diabetes. During normal operations a year prior, Michigan Medicine podiatry performed 2345 face-to-face patient visits, of which 938 (40%) were for patients with DFU. Prior to the pandemic, virtual podiatric medicine was not implemented at our institution and only a single virtual visit was performed. In addition, during the months of March–May 2019, our diabetic limb salvage inpatient service was consulted on 177 distinct inpatients with diabetic foot infections resulting in 36 minor amputations (Table 1).

Using this protocol, over 1000 EMR charts were evaluated in the first week, 200 distinct patients at highest risk for DFU complications were identified and 100 were seen within 7 days of the initial triage. Triage continued throughout the following 11 weeks and 1600 additional patients were triaged, risk stratified and directly contacted, representing 90.7% of the diabetic patients we cared for during the preceding 12 month period.

During the pandemic, outpatient volume fell by 81.9%, resulting in 425 face-to-face visits. Out of these, 416 (98%) were DFU-related,

representing a —55.7% decrease compared to the prior year. Proportionally, face-to-face visits for patients with DFU represented 1.45-fold more encounters as compared to the year prior. In addition, new outpatient volume fell by 34.8%, from 23% of encounters during normal operations to 15% during the pandemic.

Low-acuity diabetic foot concerns were suspended and managed through virtual visits. Virtual visits expanded rapidly following consolidation and 220 virtual visits were performed, an increase of 21,900% as compared to the year prior. Additionally, the diabetic limb salvage inpatient service received only 66 consults for diabetic foot infections, which is 55.6% less compared with a similar time frame from pre pandemic times. Minor amputation procedures also fell by 55.6%, to 16. Proportionally during the pandemic 24.2% of consults resulted in minor amputation whereas only 20.3% during the year prior resulted in minor amputation. This difference did not reach statistical significance ( $p > 0.05$ ).

## 4. Discussion

We provide evidence that STRIDE protocol we developed is highly effective in the risk stratification and triage of patients with diabetic foot complications, including DFU during pandemics. Podiatry excels at limb salvage and our previous data demonstrated the value of podiatry integration into the diabetes clinics at Michigan Medicine and highlights the interdisciplinary teams' work resulting in increased limb salvage and lessening the amount of diabetes-related amputations.<sup>8</sup> STRIDE protocol aligns with appropriate levels of risk to target a personalized care, with the ultimate goals to reduce risk of severe infections, amputation, and death in this highly vulnerable population. The protocol maintained appropriate social and physical distance utilizing telehealth and delivers face-to-face standard of care only as needed, preventing the spread of disease among patients and providers. The broad generalizability of the STRIDE protocol is particularly relevant given the current COVID19 trends in USA and several other countries that suggest multiple infections waves can occur until a vaccine becomes available. Thus there remains a significant need to most effectively care for this population.

Our data clearly demonstrated that once the STRIDE protocol was implemented, there was a dramatic shift toward the at-risk DFU patients, from 40% of visits during normal operations to 98% of face-to-face visits during the pandemic period. By designing and executing the protocol very rapidly in only one week, we experienced the similar low rates of DFU related hospitalization requiring minor amputations compared with pre-pandemic times.

In addition, this focused approach to defer low-risk diabetic foot concerns and non-diabetic foot concerns subsequently resulted in a broadening of Podiatry's virtual platform. The drastic increase, from zero virtual visits to 220, a 21,900% increase, reflected our ability to still care for patients who needed attention, but were not necessarily at risk of hospitalization or amputation.

Our protocol execution allowed our service to continue to provide effective care while maintaining in-person availability for our highest risk DFU patients. Without access to targeted podiatric preventive care, patients with diabetes and DFU may rapidly develop severe infections or other foot complications requiring admission, furthering the burden on an already strained health care system. Implementation of the STRIDE protocol prevented this from occurring.

Our study is not without limitation. First, we cannot fully assess the impact of the COVID-19 pandemic on DFU in only three months. This concern was ameliorated by comparing the same time period during normal operations to assess the impact of our protocol, and allowed us to account for seasonal variations seen in non-traumatic lower extremity amputation rates.<sup>26</sup> As noted, we were successful in contacting the overwhelming majority of our patients, 90.7%, using this protocol. However, patients may have perished due to unrelated factors during this time period and this investigation is still ongoing. Second, the percentage of new patients presenting for care during the pandemic decreased by 34.8%. Thus, access to care was restricted and we cannot fully



**Table 1**  
Comparison of key podiatry service metrics during the pandemic as compared to normal operation one year prior. N-number of encounters are in the middle columns with percent change demonstrated as either a positive or negative in the column on the far right.

	Normal operations (March–May 2019)	Pandemic care (March–May 2020)	Percent change
Virtual visits (n)	1	220	21,900%
Outpatient volume (n)	2345	425	–81.9%
Inpatient volume (n)	177	66	–62.75%
Minor amputations (n)	36	16	–55.6%
Minor amputation rate (% of total consults resulting in amputation)	20.3	24.2	
DFU related care (n, % of total)	938, 40%	416, 98%	–55.7%

account for new patterns of clinical deterioration. Future studies should evaluate this confounder (i.e. patients not seeking medical care) to determine if in the following months after the lockdown was over, if more patients sought help and if amputation rates subsequently rose.

*In summary*, STRIDE protocol integrated the use of novel virtual care and EMR technologies, allowed for a rapid triage of all at-risk patients, an effective delivery of personalized care based on risk stratification, and anticipated a reduction in DFU related inpatient admissions while delivering appropriate care in situation of pandemic crisis. The rapid implementation of the STRIDE protocol generated strong data demonstrating the powerful effect of the triage system to capture and care for those highest risk patients with DFU. Importantly, it provided novel evidence that these efforts maintained the same high levels of limb salvage previously established at our institution. Furthermore, our study provided a strong evidence that virtual care is in fact feasible and effective to maintain optimal care for patients with diabetic foot complications, refuting prior beliefs that virtual care would promote adverse outcomes in these patients. The need for novel and effective protocols to reduce impacts of non-COVID-19 diseases on hospital burden has never been greater, and wide dissemination of STRIDE protocol could fulfill this goal.

## Funding

This work was funded by grant number 5U01DK119083 from the National Institute of Diabetes and Digestive and Kidney Diseases to B.M.S., C.M.H., and R.P.B. The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of the NIDDK.

## Author statement

B.M.S. designed the study, wrote the manuscript, and contributed to the data analysis. C.M.H. contributed, reviewed, and edited the manuscript. G.M.R. contributed, reviewed, and edited the manuscript. M.E.M. contributed, reviewed, and edited the manuscript. R.P.B. contributed, reviewed, and edited the manuscript. B.M.S. is the guarantor of this work and, as such, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

## Prior presentation

None.

## Acknowledgments

The authors have no formal acknowledgements.

## References

- Rastogi A, Goyal G, Kesavan R, et al. Long term outcomes after incident diabetic foot ulcer: multicenter large cohort prospective study (EDI-FOCUS investigators) epidemiology of diabetic foot complications study. *Diabetes Res Clin Pract* 2020;108113.
- Pop-Busui R, Boulton AJ, Feldman EL, et al. Diabetic neuropathy: a position statement by the American Diabetes Association. *Diabetes Care* 2017;40:136–54.
- Schmidt B, Holmes C, Ye W, Pop-Busui R. A tale of two eras: mining big data from electronic health records to determine limb salvage rates with podiatry. *Curr Diabetes Rev* 2018;15(6):497–502.
- Jupiter DC, Thorud JC, Buckley CJ, Shibuya N. The impact of foot ulceration and amputation on mortality in diabetic patients. I: from ulceration to death, a systematic review. *Int Wound J* 2016;13:892–903.
- Van Damme H, Limet R. Amputation in diabetic patients. *Clin Podiatr Med Surg* 2007;24:569–82.
- Armstrong DG, Boulton AJM, Bus SA. Diabetic foot ulcers and their recurrence. *N Engl J Med* 2017;376:2367–75.
- Geiss LS, Li Y, Hora I, Albright A, Rolka D, Gregg EW. Resurgence of diabetes-related nontraumatic lower-extremity amputation in the young and middle-aged adult US population. *Diabetes Care* 2019;42:50–4.
- Schmidt BM, Wrobel JS, Munson M, Rothenberg G, Holmes CM. Podiatry impact on high-low amputation ratio characteristics: a 16-year retrospective study. *Diabetes Res Clin Pract* 2017;126:272–7.
- Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *Jama* 2005;293:217–28.
- Sloan FA, Feinglos MN, Grossman DS. Receipt of care and reduction of lower extremity amputations in a nationally representative sample of U.S. elderly. *Health Serv Res* 2010;45:1740–62.
- Rogers LC, Lavery LA, Joseph WS, Armstrong DG. All Feet On Deck—The Role of Podiatry During the COVID-19 Pandemic: Preventing hospitalizations in an overburdened healthcare system, reducing amputation and death in people with diabetes. [published online ahead of print, 2020 Mar 25]. *J Am Podiatr Med Assoc* 2020https://doi.org/10.7547/20-051.
- Carter P, Anderson M, Mossialos E. Health system, public health, and economic implications of managing COVID-19 from a cardiovascular perspective. *Eur Heart J* 2020;41(27):2516–8https://doi.org/10.1093/eurheartj/ehaa342.
- Roser M, Ritchie H, Ortiz-Ospina E, Hasell J. Coronavirus pandemic (COVID-19). Our World in Data 2020. Retrieved from: https://ourworldindata.org/coronavirus.
- Chen N, Zhou M, Dong X, et al. Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. *The Lancet* 2020;395:507–13.
- Wang D, Hu B, Hu C, et al. *Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus-infected pneumonia in Wuhan*. *Jama*: China. 2020.
- Afshinnia F, Nair V, Lin J, et al. Increased lipogenesis and impaired beta-oxidation predict type 2 diabetic kidney disease progression in American Indians. *JCI Insight* 2019;4.
- Dandona P, Aljada A. A rational approach to pathogenesis and treatment of type 2 diabetes mellitus, insulin resistance, inflammation, and atherosclerosis. *Am J Cardiol* 2002;90:27G–33G.
- Donath MY, Shoelson SE. Type 2 diabetes as an inflammatory disease. *Nat Rev Immunol* 2011;11:98–107.
- Hinder LM, Park M, Rumora AE, et al. Comparative RNA-Seq transcriptome analyses reveal distinct metabolic pathways in diabetic nerve and kidney disease. *J Cell Mol Med* 2017;21:2140–52.
- Hur J, Sullivan KA, Pande M, et al. The identification of gene expression profiles associated with progression of human diabetic neuropathy. *Brain* 2011;134:3222–35.
- Pop-Busui R, Ang L, Holmes C, Gallagher K, Feldman EL. Inflammation as a therapeutic target for diabetic neuropathies. *Curr Diab Rep* 2016;16:29.
- Lipsky BA, Berendt AR, Cornia PB, et al. 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. *Clin Infect Dis* 2012;54:e132–73.
- Lipsky BA, Aragón-Sánchez J, Diggle M, et al. IWGDF guidance on the diagnosis and management of foot infections in persons with diabetes. *Diabetes Metab Res Rev* 2016;32:45–74.
- Mills Sr JL, Conte MS, Armstrong DG, et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: risk stratification based on wound, ischemia, and foot infection (WIFI). *J Vasc Surg* 2014;59. (220–234.e222).
- Boulton AJ, Armstrong DG, Albert SF, et al. Comprehensive foot examination and risk assessment: a report of the task force of the foot care interest group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists. *Diabetes Care* 2008;31:1679–85.
- Armstrong DG, Lavery LA, Van Houtum WH, Harkless LB. Seasonal variations in lower extremity amputation. *J Foot Ankle Surg* 1997;36:146–50.