Diabetes And Preventable Complications: Impact On The Health-care System And The Associated Economic Burden Beyond Direct Health-care Costs

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Abstract: Diabetic foot ulcers represent a prevalent complication of diabetes mellitus, imposing a substantial clinical and economic burden on the global health-care system.[1] The enormous economic toll of diabetes continues to burden society through direct medical and indirect costs. By directing research efforts appropriately, we can make significant strides in preventing diabetic foot complications, improving patient outcomes and reducing the overall burden on health-care systems and individuals.

Key words: *diabetic foot ulcers, health systems impact, associated costs, economic burden, prevention.*

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Introduction

Diabetic foot ulcers represent a prevalent complication of diabetes mellitus, imposing a substantial clinical and economic burden on the global health-care system.[1] Diabetes-related foot infections occur in approximately 40% of diabetes-related foot ulcers and cause significant morbidity. The convergence of neuropathy and ischemia, characteristic of the diabetic foot, results in neuropathic and ischemic foot ulceration, as well as Charcot neuroarthropathy, often complicated by infections, potentially culminating in amputations and heightened mortality.[2]

About 3.0 million Canadians (8.1%) were living with diagnosed diabetes in 2013–2014.[3] In 2017, 7.3% of Canadians aged 12 and older (roughly 2.3 million people) reported being diagnosed with diabetes.[4] Among Canadians, 30% live with diabetes or prediabetes; 10% live with diagnosed diabetes, a figure that climbs to 14% when cases of undiagnosed type 2 diabetes are included.[5] Diabetes complications are associated with premature death and can reduce lifespan by five to 15 years.[5] In fact, foot problems are the leading cause of hospitalization for Canadians living with diabetes.[6] Research estimated the total estimated cost of diagnosed diabetes in the US in 2022 to be $412.9 billion USD, including $306.6 billion in direct medical costs and $106.3 billion in indirect costs attributable to diabetes. For cost categories analyzed, care for people diagnosed with diabetes accounts for one in four health-care dollars spent in the US, 61% of which are attributable to diabetes.[7] Major contributors to indirect costs in the US are reduced employment due to disability ($28.3 billion), presenteeism ($35.8 billion) and lost productivity due to 338,526 premature deaths ($32.4 billion).[7]

Reduced circulation and sensation in the feet, common in diabetes, necessitate daily foot examination and professional fitting of shoes to prevent complications. Despite preventive measures, more than one million people globally undergo lower extremity amputations (LEA) annually due to diabetes, resulting in a limb loss every 20 seconds.[8] The economic burden of limb amputation includes direct costs (hospitalization, surgery, prosthetics) and indirect costs (lost productivity, premature mortality), highlighting the substantial impact on health-care resources. The majority of foot problems diagnosed in people with diabetes could have been avoided through daily foot care and proper shoe selection. Many people with diabetes have reduced circulation or sensation in their feet (neuropathy) and are not able to feel if something may be in their shoe or if the shoe itself is irritating their foot. To avoid the development of wounds or ulcers, it is vital that people living with diabetes visually examine their feet daily[6] and, when purchasing shoes, have them professionally fitted rather than relying on how their feet 'feel'.

Every year, more than one million people undergo a lower extremity amputation (LEA) secondary to diabetes, resulting in a limb loss every 20 seconds worldwide.[8] Of all the lower extremity amputations in persons with diabetes, 85% are preceded by a foot ulcer. The mortality at five years for an individual with a diabetic foot ulcer is 2.5 times as high as the risk for an individual with diabetes who does not have a foot ulcer.[1] One possible approach to estimate the economic burden of limb amputation due to diabetes, like any other disease, is to use the following formula:

Economic Burden = Direct Costs + Indirect Costs + Intangible Costs.

Note, these cost-element (inputs or factors) vary by jurisdiction, depending on health-care costs and economic productivity.

Direct Costs

Direct costs are the expenses associated with the diagnosis, treatment and prevention of limb amputation due to diabetes, such as hospital-

Figure 1: Disability Adjusted Life Years (DALY). Source: Public Health England. Accessed at: https://www.scotpho.org.uk/comparative-health/burden-of-disease/why-burden-of-disease/.

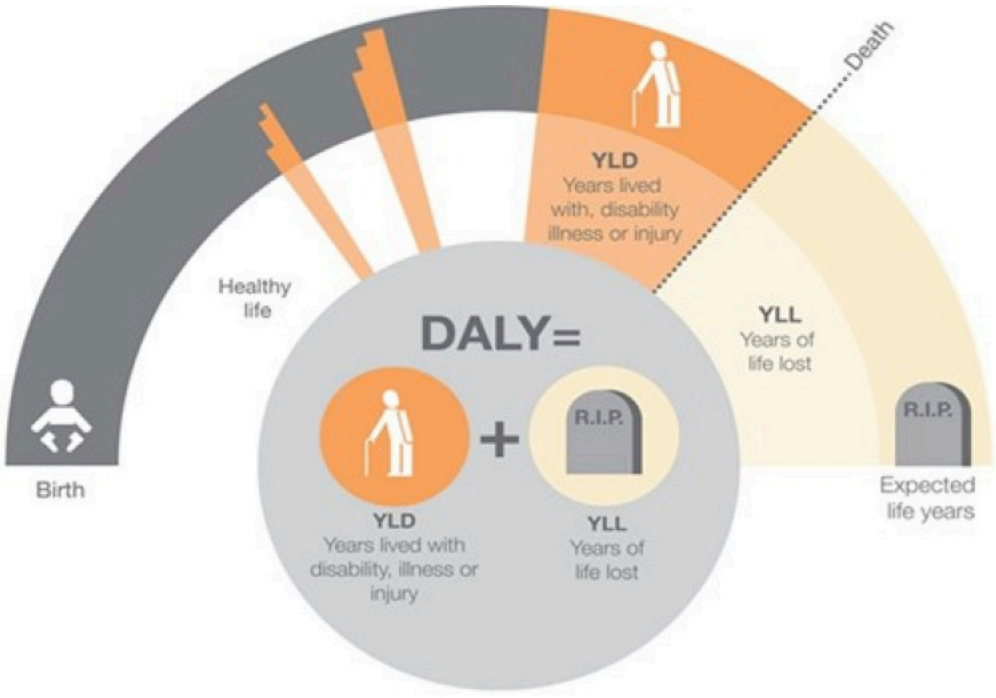
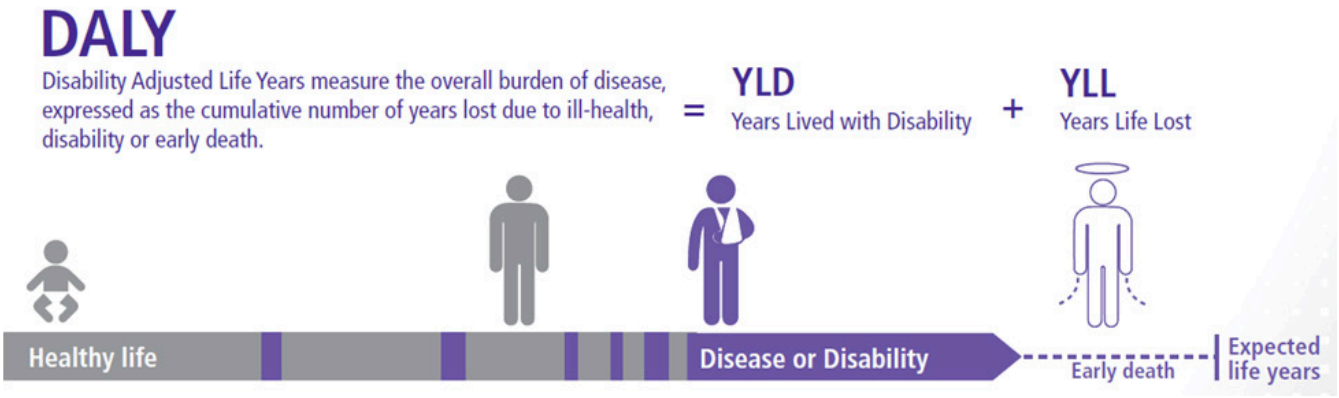


Figure 2: Disability Adjusted Life Years (DALY). Source: Wiki Commons. Accessed at: https://nccid.ca/publications/understanding-the-measurement-of-global-burden-of-disease/



ization, surgery, prosthetics, rehabilitation and medications. Indirect costs are the losses incurred by individuals and society due to reduced or lost productivity, such as absenteeism, disability, early retirement and premature mortality. Intangible costs are the non-monetary impacts of limb amputation due to diabetes on the physical and mental well-being of individuals and their families, such as pain, anxiety, depression and reduced quality of life. The diabetic foot is a significant contributor to the global burden of disability and reduces the quality of life. It remains a considerable public health problem.

Medical Costs: Direct, Indirect And Intangible

The cost-of-illness study is considered to be an essential evaluation technique in health care. By measuring and comparing the economic burdens of diseases to society, such studies can help healthcare decision-makers set up and prioritize healthcare policies and interventions. Using economic theories, various study methods are introduced[9] that are generally applicable to most disease cases for estimating the costs of illness associated with mortality, morbidity, disability, and other disease characteristics. It also presents concepts and scopes of costs along with different cost categories from different research perspectives in cost estimations. By discussing the economic grounds of the cost-of-illness study, the reported results represent useful information about several evaluation techniques at an advanced level, such as cost-benefit analysis, cost-effectiveness analysis and cost-utility analysis. [9]

The direct medical costs associated with foot ulcers are sustainable and encompass a range of expenses, including hospitalization, outpatient care, wound care supplies, medications, surgeries and amputation. Studies have shown that the cost of managing a single diabetic foot ulcer episode can vary widely, but it is generally higher for patients who require hospitalizations, surgical intervention or amputation. Long-term management of chronic ulcers contributes significantly to the overall economic burden.

In a multicentre study of all diabetic foot ulcer patients admitted to hospitals in the Greater Toronto Area from 2010 to 2015, diabetic foot ulcer admissions incurred the highest mean cost per patient ($22,754 CDN) when compared to non-diabetic foot ulcer diabetes ($8,350).[10] Using adjusted linear regression, diabetic foot ulcer admissions demonstrated a 49.6% greater mean cost of care than non-diabetic foot ulcer-related diabetes admissions. Direct costs of care for diabetes in general were $237 billion USD in 2017.[11] This is compared to $80 billion for cancer in 2015. As up to one-third of the direct costs of care for diabetes may be attributed to the lower extremities, these are also readily comparable.[11] The report, by Armstrong et al. (USA),[11] compared the five-year mortality and direct costs of care for people with diabetic foot complications to cancer. The report found that five-year mortality for Charcot, DFU, minor and major ampu-

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tations were 29.0%, 30.5%, 46.2% and 56.6%, respectively. This is compared to 9.0% for breast cancer and 80.0% for lung cancer. The report also estimated that the direct costs of care for diabetes in general were $237 billion USD in 2017, which is comparable to $80 billion for cancer in 2015.

Besides the direct medical expenses, the indirect costs related to diabetic foot ulcers result from reduced productivity, disability and decreased quality of life for both patients and caregivers. Indirect costs include:

- Increased absenteeism ($3.3 billion)
- Reduced productivity while at work ($26.9 billion) for the employed population
- Reduced productivity for those not in the labour force ($2.3 billion)
- Inability to work as a result of disease-related disability ($37.5 billion)
- Lost productive capacity due to early mortality ($19.9 billion).[12]

People with diabetes have a 34% lifetime risk of developing a diabetic foot ulcer. And when we look at the costs of diabetic foot ulcers, it's a significant jump in these high-risk patients. Patients without diabetic foot ulcers cost around $17,000 each year. Patients with diabetic foot ulcers — $58,000 USD. This demonstrates that there's a clear link between health-care costs and diabetic foot ulcers. A big, costly link.[13]

Diabetic foot ulcers are actually more expensive than the five most costly forms of cancer. Totaling over $100 billion USD.[13] Most are familiar with the costs of cancer and the toll that cancer has on our nations. But diabetic foot ulcers are often swept under the rug in larger conversations about health-care spending and costs, and this needs to change.

To calculate each component of the economic burden, we need data on the prevalence and incidence of limb amputations due to diabetes in a jurisdiction, the average costs and outcomes associated with different types and levels of amputation, and the valuation methods for measuring intangible costs. Some of these data may be available from existing sources such as administrative databases, surveys, studies and reports. However, some data may be missing or incomplete, requiring assumptions or extrapolations.

For example, according to a report by Diabetes Canada,[14] in 2011-12, diabetes-related foot wounds contributed to about one-third of all amputations performed in hospitals across Canada. The report also estimated that the average cost per hospitalization for a lower extremity amputation (LEA) was $21,000 CDN in 2011-12. However, this cost does not include the costs of prosthetics, rehabilitation, medications, or follow-up care. Moreover, this cost does not account for the differences in the type (LEA or upper extremity amputation [UEA]) and level (major or minor) of amputation, which may have different implications for the outcomes and costs.

A recent study by Essien et al.[15] explored the trends of LEA and UEA by level of amputation, sex and age over 14 years in Saskatchewan, Canada. The study found that LEA predominated over UEA over the study period, with minor LEA increasing and major LEA decreasing. The study also found that males were twice as likely to undergo LEA than females, and that LEA rate increased with increasing age. However, this study did not provide any information on the costs or outcomes associated with different types and levels of amputation.

Intangible Costs

Another challenge in estimating the economic burden of limb amputation due to diabetes in a jurisdiction is to measure the intangible costs. Intangible costs are difficult to quantify because they involve subjective perceptions and preferences that may vary across individuals and contexts. One possible method to measure intangible costs is to use health-related quality of life (HRQoL) instruments that capture the physical, mental and social aspects of well-being. HRQoL can be expressed as a utility score that ranges from 0 (death) to 1 (perfect health), or as a disability-adjusted life year (DALY) that combines years of life lost due to premature mortality and years lived with disability (See Figures 1 and 2).

To estimate the intangible costs of limb amputation due to diabetes, we need data on the HRQoL or DALYs associated with different types and levels of amputation, as well as the general population norms for comparison. We also need data on the willingness to pay (WTP) for a unit change in HRQoL or DALYs, which reflects the monetary value that individuals or society place on health outcomes. However, these data may not be readily available or consistent across sources.

A study by Sassi[15] compared the methods and results of calculating quality-adjusted life years (QALYs) and DALYs, which are two common measures of health outcomes that incorporate both quantity and quality of life. The study explained how to calculate QALYs and DALYs, and how they differ in terms of assumptions, perspectives, and values. The study also illustrated the relationship between QALYs gained and DALYs saved using two examples: the prevention of tuberculosis and the treatment of bipolar depression.[16]

A report by NICE[17] described the principles and methods for assessing cost-effectiveness in clinical guidelines, using QALYs as the preferred measure of health outcomes. The report also discussed the sources and methods for measuring and valuing health-related quality of life (HRQoL) and willingness to pay (WTP) for a unit change in QALYs. The report recommended using the EQ-5D as the preferred instrument for measuring HRQoL in adults, and obtaining preference data from a representative sample of the UK population for valuing changes in HRQoL.

A review by Brazier et al.[18] provided an overview of the methods and challenges of measuring and valuing health outcomes in economic evaluation. The review discussed the advantages and disadvantages of different instruments for measuring HRQoL, such as EQ-5D, SF-6D, HUI and AQoL. The review also compared different methods for eliciting preferences for health states, such as standard gamble, time trade-off, rating scale and discrete choice experiments.

A study by D. Parker et al. states that in the US diabetes is responsible for 20% of cardiovascular deaths (excluding cerebrovascular deaths), 26% of deaths with cerebrovascular disease listed as the primary cause and approximately equal to 45% of deaths with renal failure listed as the primary cause.[7]

Estimating the economic burden of limb amputation due to diabetes is a complex and challenging task that requires comprehensive and reliable data sources, rigorous analytical methods and transparent assumptions. The results may vary depending on the scope, perspective, time horizon, discount rate and sensitivity analysis used in the estimation. The results may also have limitations and uncertainties due to data gaps and quality issues. Nevertheless, estimating the economic burden of limb amputation due to diabetes in Canada can provide valuable information for policymakers, health-care providers, researchers, patients and caregivers to understand the magnitude and distribution of the problem, identify priority areas for intervention, evaluate alternative options for prevention and management and allocate resources efficiently and equitably.

Amputations And Long-term Consequences

One of the most severe consequences of diabetic foot ulcers is lower extremity amputation, significantly escalating direct, indirect and intangible costs. Amputations entail prolonged hospital stays, post-operative rehabilitation and the necessity for prosthetic devices. Furthermore, individuals undergoing amputations face heightened risks of mortality, diminished quality of life and increased health-care utilization.

In Canada, approximately 14 diabetes-related amputations are performed daily, totalling over 5000 amputations annually. The five-year mortality rate following amputation ranges from 45% to 80%. Alarmingly, 40% of diabetes patients are reported to be unaware of or unable to recognize risk factors or practice self-care behaviours to prevent diabetic foot complications. Additionally, comorbid depression affects 20-40% of individuals with diabetes.[17]

A population-based study in Ontario, Canada identified a decline in diabetes-related complications, including acute myocardial infarction, stroke, end-stage renal disease and hyperglycemia

crisis, over the last 20 years. However, it highlighted a surge in amputations over the past decade.[16] The escalating number of amputations is attributed to the increasing prevalence of diabetes, peripheral artery disease and inadequate coordination of foot and wound care. Despite discouraging statistics, the International Working Group on the Diabetic Foot (2019) emphasizes the potential for reducing amputations through well-organized diabetic foot care teams, limb preservation teams and informed self-care practices by patients.

Prevention And Treatment

Numerous studies have explored the cost-effectiveness of interventions to prevent and treat diabetic foot ulcers. These interventions encompass patient education, regular foot screening, offloading devices, wound dressings, antibiotics, revascularization procedures and advanced therapies such as growth factors and hyperbaric oxygen therapy. Despite perceived high upfront costs for preventive measures, evidence suggests substantial cost savings by reducing ulcer incidence, amputations and related complications.

Conducting a comprehensive medical history is crucial for identifying undisclosed medical conditions and potential risks to wound healing. A thorough patient history should encompass active and past medical conditions, including complications like retinopathy, nephropathy, neuropathy and vasculopathy. Smoking history is particularly relevant, given its association with peripheral arterial disease (PAD). Additionally, identifying barriers to self-managed and clinician-delivered care, such as visual or auditory impairment, is essential for effective foot assessments and instructions. Recognizing these barriers enables the implementation of appropriate care plans. The risk of foot ulceration in individuals with diabetes rises in the presence of peripheral neuropathy, previous ulceration or amputation, structural deformity, limited joint mobility, PAD, onychomycosis and elevated glycosylated hemoglobin (A1c) levels.[19] Loss of sensation, often assessed using a 10 g Semmes-Weinstein monofilament, is a significant predictor of future foot ulceration and lower-extremity amputation.

Clinicians are encouraged to use a validated foot screen in clinical practice. Foot screening tools provide a uniform approach that helps ensure that a comprehensive foot exam is completed. There are many validated diabetic foot-screening tools available, but a tool can only be effective if clinician education and organizational and system supports are in place[20] and if the tool is 'evidence-informed and relevant to the characteristics of the target population'. There are multiple tools for the clinician to consider, including the *Inlow 60-second Diabetic Foot Screen,*[21] which includes three parts: assessment, risk stratification and care recommendations.

The primary objective of diabetic foot care is to prevent diabetic foot ulcers (DFUs) and subsequent lower extremity amputations (LEAs). The involvement of an Inter-Professional Team (IPT), including a podiatrist, facilitates complementary work and synergy of skills and knowledge to achieve optimal outcomes for patients.[22]

The results of this review support the concept that IPTs with podiatrists lead to a statistically significant reduction of LEAs (total and major LEAs) compared to interventions without MDTs. After qualitative analysis, authors of the included studies examining minor LEAs as outcomes have shown that there are more minor LEAs with MDT interventions. However, upon analysis of results in relation to other severities of LEAs (major versus minor) and with total LEAs, the level of LEAs may decrease with an IPT with podiatry management. There is a 31% relative risk reduction in undergoing a LEA, either major or minor, with MDT management with podiatry for people at risk for diabetic foot. Considering only major LEAs, the relative risk reduction was of 55%. These results are clinically meaningful in favour of the intervention, considering the high five-year mortality rate and the low quality of life of patients with diabetes who undergo LEAs.[11,22]

Diabetic foot ulcers often become chronic wounds, requiring prolonged and costly care. The management involves a multidisciplinary approach, including wound care specialists, dia-

betologists, vascular surgeons and podiatrists. The need for continuous monitoring and treatment can significantly impact health-care resources.

Despite advancements, there is an ongoing need for health services research and research programs into the specific causes of amputation, including vascular, neuropathic factors, and preventive foot care practices.[12] Clinicians must also renew their efforts to organize clinical processes for identifying at-risk feet and applying preventive measures.[23]

Early identification of high-risk feet is imperative to decrease rates of mortality and morbidity. An interprofessional approach involving physicians, nurses and foot care specialists is often necessary to address the diverse needs of patients.[24]

Future Direction

The enormous economic toll of diabetes continues to burden society through direct medical and indirect costs.

Using the formulas provided, jurisdictional estimates can be calculated.

Given the significant clinical and economic burden, emphasis should be placed on preventive strategies. This includes patient education on foot care, regular foot examinations, glycemic control and lifestyle modifications. Early detection of foot issues and timely intervention can prevent the progression to severe complications.

Future research should focus on refining methodologies for assessing the economic burden of diabetic foot ulcers, considering standardized approaches to cost estimation, data collection and outcome measurement. Additionally, investigating innovative interventions and technologies that can further reduce the incidence of foot ulcers and associated complications is crucial for improving patient outcomes and mitigating the economic impact.

Other Opportunities

On a related note, future research to prevent diabetic foot problems should focus on several key areas to enhance our understanding and develop more effective preventive strategies. Here are some directions for future research. While not directly related to the topic of 'Economic Burden', these opportunities should be explored by the larger field:

Early Biomarkers and Predictive Models: Explore and identify early biomarkers that can predict the risk of diabetic foot complications. This can aid in the early identification of individuals at higher risk, allowing for timely intervention.

Develop predictive models that take into account multiple factors such as glycemic control, neuropathy, vascular status and patient-specific variables to estimate the risk of developing diabetic foot complications.

Advanced Imaging Technologies: Investigate and develop advanced imaging technologies for early detection of structural and functional changes in the foot. This includes techniques such as advanced ultrasound, MRI, and infrared imaging to identify early signs of neuropathy, vascular compromise, or inflammation.

Personalized Medicine Approaches: Explore personalized medicine approaches to diabetic foot prevention. This involves tailoring interventions based on an individual's unique characteristics, genetic predispositions and response to treatments.

Wearable Technologies: Investigate the use of wearable devices and sensor technologies to continuously monitor foot temperature, pressure distribution, and gait patterns. These technologies can provide real-time data for early detection of potential issues and enable timely interventions.

Patient Education and Behavioural Interventions: Conduct research on increasing the effectiveness of methods of patient education and behavioural interventions to promote foot self-care and adherence to preventive measures. Understanding the psychological and social factors that influence patient behaviour is crucial for designing targeted interventions.

Telehealth and Remote Monitoring: Explore how to improve the effectiveness of telehealth and remote monitoring in diabetic foot care. Investigate how technologies such as telemedicine, mobile applications and remote monitoring devices can facilitate regular follow-ups, early

detection of problems and timely communication between health-care providers and patients.

Interventions Addressing Peripheral Neuropathy: Investigate novel interventions for preventing and managing peripheral neuropathy, a significant contributor to diabetic foot complications. This may include pharmacological agents, neuroprotective strategies and regenerative medicine approaches.

Community-based Interventions: Conduct research on community-based interventions to promote foot health. Engage community health workers, educators and local health-care facilities to deliver preventive education and early screening in at-risk populations. Develop early warning sentinels in the family and circle of care.

Healthcare System Integration: Explore ways to integrate diabetic foot care into broader health-care systems. This includes optimizing communication and collaboration between primary care providers, endocrinologists, podiatrists, vascular specialists, and other relevant health-care professionals.

Long-term Outcomes and Cost-effectiveness: Assess the long-term outcomes and cost-effectiveness of various preventive strategies. Evaluate the impact of preventive measures on reducing the incidence of diabetic foot complications, amputations and associated health-care costs.

By directing research efforts toward these areas, we can make significant strides in preventing diabetic foot complications, improving patient outcomes and reducing the overall burden on health-care systems and individuals. ■

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