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Economic Modelling of Best Evidenced Podiatry Care for the Diabetic Foot from the South Australian Healthcare Perspective: A Decision Tree Sensitivity Analysis

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Abstract

Objective: To develop a decision tree model to estimate the cost-effectiveness of best-evidenced podiatric interventions for people with diabetes from the South Australian healthcare perspective. We explored the hypothesis that the investment required to offer best-evidenced podiatric care is offset by potential downstream savings, through prevention of ulcers, or hospitalisation for sequelae of infection.

Methods: Recommendations from current clinical practice guidelines were extracted for best-evidenced podiatric care for patients with diabetes. Clinical pathways were constructed to describe usual and best-evidenced podiatric care options in community and hospital. Local South Australian podiatry service delivery data, and costs of care, were collated and mapped to the pathways adopting the healthcare perspective. The quality of life years (QALY) data was extracted from the literature. A Markov-based 5 years simulation was done for a hypothetical diabetic patient using TreeAge Pro 2016 software.

Results: Best-evidenced podiatric care including: a risk-appropriate number of visits to podiatrist, patient education, foot care, footwear and multidisciplinary team management, is cost-effective. The average cost and QALY of best-evidenced practice podiatric care is ($31,424.86, 3.33QALY) and ($34,085.72, 3.01QALY) for usual care. A per-patient investment of $6.86K over five years in best-evidenced podiatric care for low- and intermediate-risk patients with diabetes would generate savings of approximately $9.43K per-patient, by reducing avoidable ulcers, infections and amputations (savings-to-cost ratio=1.37). Best-evidenced podiatric care was 99% dominant over usual care.

Conclusions: Promoting and funding best-evidenced podiatric care for every patient with diabetes is significantly cost-saving in terms of avoided complications.

Keywords: Podiatry care; Best-evidenced; Decision tree; Economic evaluation

Introduction

The economics of diabetes

Worldwide, diabetes mellitus (DM) is an increasingly-prevalent chronic disease [1,2]. It is estimated that DM will affect approximately 300 million people globally by 2025 [3]. Recent data from the Australian Bureau of statistics suggests that one million people in Australia have DM [4]. In South Australia in 2009, this number approximated 150,000, reflecting 6.8 newly-diagnosed DM cases per 1000 adults per-year [5,6]. In South Australia, the rate of diabetes-related amputations has been consistently high over the last two decades [6-8]. Payne 2000 [6] showed that from 1995-96 to 1997-98 in South Australia, this rate was 20.68 (95% confidence interval (CI):17.18-24.98) compared to 13.97 (95% CI: 11.98-15.87) for the whole of Australia. In 2012-13, the South Australian rate was 17% higher than the Australian average (27 *vs*. 23 per 100,000) [7].

In line with the increasing prevalence of DM, is rising healthcare expenditure required to manage DM complications. In Australia in 2012, the expected cost of care of a person with DM who did not have complications was $3,500 to $4,000 per-year, whilst it cost between $7,000 and $16,700 per-year to manage people with DM complications [2,9]. The total economic burden of DM in Australia has been estimated at $6 billion, including healthcare costs, Commonwealth subsidies, caregiver's cost and productivity loss [9]. A recent study reporting on a Markov simulation model suggests that optimal care for diabetic foot ulcers (DFU) in Australia could result in 2.7 billion savings over five years [10].

Many DM-related costs are avoidable [11,12]. The data for potentially-avoidable hospital admissions in Australia indicates that 63.8% (353, 000 admissions) are attributed to chronic diseases [11]. South Australian and Australian hospital admission data from Australian Institute of Health and Welfare (AIHW) indicates that DM-related admissions accounted for 25% of the avoidable hospital admissions associated with chronic disease [5].

The diabetic foot

Foot problems are common DM complications [12,13]. These include macrovascular complications (e.g. peripheral arterial disease); microvascular disease; neuropathy; foot deformity; oedema; and an

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increased susceptibility to infection. Once established, and without careful intervention, the impact of DM on the health and function of the 'diabetic foot' can escalate. For instance, peripheral neuropathy can result from an altered metabolic pathway which occurs in the presence of raised blood glucose levels, often exacerbated by microvascular pathology and subsequent decreased vascular supply to nerves [14]. The metabolic consequences of DM may also impact on soft tissue (muscles, tendons, ligaments and other connective tissues). One such sequelae, soft tissue glycosylation, can subsequently impact on foot biomechanics and gait characteristics, and the ability to withstand external and internal forces [15]. This in turn, contributes to deformity, which increases foot plantar pressures [13,15]. Moreover, sequelae of motor neuropathy are muscle atrophy and weakness, which underpin further deformity [14,16]. This, combined with autonomic system dysfunction, can affect skin integrity and decrease and/or displace the plantar fat pad, affecting the foot's ability to withstand the abnormal external forces incurred by DM-related gait characteristics [17]. When even minor trauma occurs to the 'diabetic foot', there is likely to be breakdown of the skin and underlying soft tissues, and subsequent ulceration [14,17]. Such trauma may occur via minor and often unidentified incidents resulting from repetitive aberrant pressures in the foot. Between 15% and 25% of all people with DM will develop ulceration in the foot or lower limb over their lifetime [18-21]. Approximately 56% ulcerations become infected, and 20% patients with infected ulcers will ultimately require an amputation [15,17]. This significantly increases individuals' disability, reduces quality of life [22] and incurs significant ongoing costs not only to the healthcare system, and also to society in terms of potentially reduced productivity [1,9].

Podiatric care for the diabetic foot

Best-evidenced podiatric care should prevent diabetic foot ulcers from occurring [18-19,21-25]. Even if ulcers do form, with best-evidenced podiatric care, ulcer severity will be minimised, and ulcers should heal [13,22-26]. Best-evidenced podiatric care for DM normally takes an integrated multi-pronged approach, comprising comprehensive foot assessment of skin and nail health, neurological and vascular status, biomechanics and presenting deformities, management of presenting dermatological pathology if required, prescription of therapeutic footwear or podiatric in-shoe supports, and patient education regarding foot self-assessment and DM self-management [12-15,22-29].

Access to podiatric care

People with DM can receive podiatric care in Australia through different routes [22]. They can consult private podiatrists at their own cost, or access publicly-funded care through community-based public services (such as hospital outpatients or community clinics). Patients with DM may access podiatry services through the limited Medicare-funded Chronic Disease Management Program (CDMP) for which General Medical Practitioners (GPs) are the gatekeepers [22,26]. This schedule allows them to receive up to five AH visits (total) for one chronic disease, in a calendar year. GPs determine (with variable patient and AH provider input) the specific type and number of AH services required to manage the patient's chronic disease problems. The Practice Incentive Program (PIP) provides financial rewards to GPs when their patients complete an annual cycle of care that includes two-foot assessments [27]. In Australia, only 18% of patients with DM were reported as having completed the annual cycle of care in 2009-10 [28].

There is scant evidence to support which AH services should be provided for DM management, or to guide best practice referral, and communication between GPs and podiatrists. Moreover, there is little information about how well Australian podiatric care complies with recommended best practice [26].

Foot-risk classifications

Podiatrists classify diabetic feet into well-defined risk categories (low, intermediate or high-risk (in the absence ulceration)) [12,18,19,22,25,30,31]. Podiatric care is delivered according to risk category. This involves increasing frequency of monitoring, specific advice on maintaining skin integrity and management of skin and nail pathology, pressure management and prevention strategies, as well as education and advice regarding DM self-care and foot self-management [22,24,25,30-32].

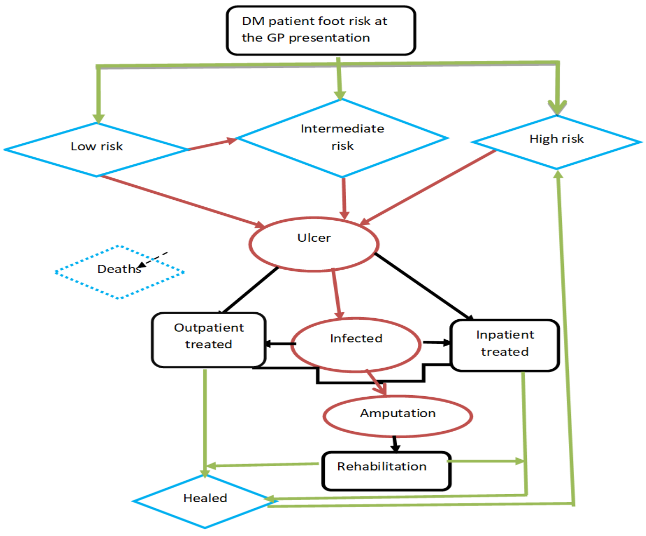
According to current clinical guidelines [18-19,31], for a low risk DM patient who presents with no foot-related complications, appropriate podiatric care is one consultation every year. For intermediate-risk DM patients who present with one foot-related diabetic complication per year (but not including a foot ulcer or a history of ulceration or amputation), appropriate care is two-six consultations. For high-risk DM patients who present with two or more foot-related diabetic complications and/or a history of ulceration or amputation, appropriate podiatric care is provided in 6-12 visits per year [18-19,31].

When an ulcer is present, more frequent podiatric visits may be necessary [22]. For ulcers which do not heal within four weeks, or which result in complications, evidence-based practice guidelines recommend immediate referral to a multidisciplinary team comprising a podiatrist, diabetes physician, diabetes nurse specialist, vascular surgeon, orthopaedic surgeon, radiologist, wound care nurse, and footwear technician [18,22,24-25,30,32]. Patients with active ulcers and high risk of infection may need to be treated regularly in hospital outpatient clinics, or as inpatients. Local sharp debridement of pressure-related/neuropathic wounds may be required to improve ulcer healing [30-34]. There is no current evidence regarding the optimal frequency and extent of debridement, however one study recommends non-surgical sharp debridement by podiatrists every 1-2 weeks [35]. Ulcer complications can include gangrene, limb-threatening ischemia, exposure to bone, joint or tendon, ascending cellulitis, systemic symptoms of infection, and/or osteomyelitis [30-36]. Patients with these ulcer complications are deemed to be at extreme-risk of irreversible tissue damage.

South Australia is the Australian state with the highest rate of leg amputations from complications of DM. This paper reports on an economic decision-tree model to evaluate the cost-effectiveness of best-evidenced podiatric care compared with usual care, for South Australians with DM.

Methods

The decision-tree model applied risk categories for diabetic feet (as defined in the literature) [12,18-19,22,25,30-31] for hypothetical patients with DM, who present to a GP for management. Each type of DM patient has variable likelihood of developing diabetic foot ulcers, which could subsequently become infected, and could result in the need for hospital treatment (outpatients or inpatients) [37]. Furthermore, all patients with a healed ulcer (whether it was infected or not), or who received an amputation because of unhealed ulcers, require continual monitoring as they remain at high-risk. In the absence of an ulcer, all patients should continue to be monitored in their relevant risk category (i.e. low risk or intermediate risk) (Figure 1).



Green: Decisions of follow up in the specific risk category.
Red: Development of foot related complications requiring review of care in transition phase.
Blue: Beginning or end of a cycle of care. Blue dash indicates the non-survivals during the cycle.
Black: Decision of care for patient with active ulcer and amputation.

Figure 1: Diagram of pathways of podiatric care and risk of foot complications.

Scenarios

We assumed two scenarios for the purpose of the modelling: usual podiatric care, and best-evidenced podiatric care. Usual podiatric care was hypothesised as being variable, influenced by factors such as available public funds; ease of access to podiatrists (public or private); podiatrist compliance with evidence-based practice; variable knowledge by GPs of best practice podiatric care, and the importance of referral to podiatry, the limited Medicare CDMP funding and variable patient health literacy, engagement and compliance in their own care.

Within the South Australian public system, the consequences of demand, priority and available funding mean that podiatry services provided in tertiary outpatient or acute care settings are often restricted to treatment of extreme-risk patients with DM (those patients with current ulcerations and/or infections). Consequently, low to intermediate-risk patients may need to rely on the private system to access podiatry services, if they access any, at all. Even in the instance where patients can access podiatry services using CDMPs, GP referral decisions vary. GPs may not refer patients to podiatry at all, they may not refer for the recommended number of podiatry visits for the DM risk categories, or even if they designate all five available AH visits as podiatry visits, this number may be insufficient for podiatrists to provide best-evidenced care for high-risk patients. Patients with DM may also incur direct personal costs for additional podiatry appointments if required, gap payments to top-up insufficient Medicare rebates, and/or to purchase consumables such as orthoses or specialised footwear.

Usual podiatric care was thus assumed to be where:

Newly-diagnosed DM patients with low, intermediate and high risk of podiatric foot complications received no GP referral to podiatrist, even when these patients were participating in a CDMP;

Patients with active ulcers received variable treatment (type and frequency) as hospital outpatients or inpatients; and

Consumables (such as footwear and orthotics) may not be offered as a preventive intervention, or even when offered, they may not be affordable.

Best-evidenced podiatric care

Information on this type of care provided in outpatient, community or private practice settings was extracted from Australian national guidelines for the prevention, identification and management of foot complications in diabetes [18], other DM guidelines and podiatry professional practice statements [24-25,30-33,35], primary research [19,21-22,26,34,36] and economic estimations of risk [38-40]. As noted earlier, this involved different levels of service provision depending on risk of foot complications.

Population data

The model population comprised hypothetical patients who had been diagnosed with diabetes at the GP practice and were classified has having low, intermediate or high risk of foot ulcers or other foot complications. The prevalence estimates of low risk of foot complications (no obvious foot problems), intermediate risk (the presence of neuropathy, or peripheral arterial disease) and high risk (presence of two or more skin lesions, and or history of ulcer or amputation) were extrapolated from the DM Australian population [4,41] (as the proportion of patients with, and without, complications (co morbidity) or history of complications). South Australian prevalence estimates of foot ulcer and the likelihood of infection, hospitalization and amputation were used with relative risks or odds ratios to compute the likelihood of DM patients experiencing these complications in specific risk groups (Table 1).

For example, in usual podiatric care, the risk that an ulcer occurs in the intermediate group (or high-risk group) was equal to the relative risk of ulcer in this group multiplied by the probability of an ulcer occurring in the low risk group (designated as the comparison group). In the same way, the probability of an existing ulcer healing in the intermediate group (or high-risk group) was respectively computed using the transformation formula involving the odds ratio, and the probability of ulcer healing in the low risk group [42]. In best-practice podiatric care, we used either the odds ratio or the relative risk for effectiveness of interventions (best practice compared to usual care) to estimate the probability of healing, amputation and ulcer development in the different DM risk categories.

Costs

Table 1 reports the baseline cost data, relevant distribution assumptions, the data sources and relevant calculations using South Australian hospital data for Australian-refined diagnosis- related groups (AR_DRG), Medicare Benefit Schedule (MBS) data [43], Department of Veteran Affairs (DVA) fees schedule [44], and online resources [45-48]. Table 2 outlines the basic cost items used for analysis in usual care and best evidence care.

Clinical evidence data

Clinical evidence derived from the literature [38,39,49] was layered with expert opinion, to underpin probability assumptions (Table 1). Because of uncertainty around the costs, the probabilities of risk, and the effectiveness of podiatric interventions for different risk categories of DM, specific distribution functions were imposed on the variables of costs, and transitions between health states, to assist subsequent modelling.

Description	Baseline	Distribution	Source
Population data			
Incidence of ulcer	0.03; [range:0.01-0.06]	Beta (mean=0.03, se=0.013]	[23,36,39]
Ulcer incidence Intermediate risk	2.03; [RR=2.03, 95%CI: 1.50-2.76]	Lognormal (mean=0.71, se=0.15)	[57]
Ulcer incidence High risk	2.57; [RR=2.57, 95%CI: 1.60-4.12]	Lognormal (mean =0.94, se=0.24)	[57]
Ulcer infection	0.47; [range: 0.12-0.81]	Beta (mean=0.47, se=0.18)	[18,34,35]
Healing ulcer low risk	0.19; [range: 0.16-0.22	Beta (mean=0.19, se=0.15)	[13]
Healing in infected ulcer	0.3; [OR=0.3, 95%CI: 0.16-0.56]	Lognormal (mean=-1.20, se=0.32)	[58]
Healing in ulcer in high and intermediate risk	0.1; [RR=0.1, 95%CI: 0.08 0.34]	Lognormal (mean=-2.3, se=0.37)	[10,58]
Amputation rate for SA	0.0001075; [95%CI: 0.000104- 0.000111]	Beta (0.00011, se=0.000002)	[5,6,7,8]
Amputation in diabetes	1.1; [RR =1.1, 95%CI: 1.05-1.15]	Lognormal (mean=0.14, se=0.095)	[8]
Amputation Intermediate and high risk	3.3; [RR=3.3,95%CI: 1.05-10.26]	Lognormal (mean=2.33, se=1.19)	[59]
Amputation diabetes and DFU	1.25 [Range= 1.06-1.43]	lognormal (mean=0.36, se=0.22)	[59]
Prevalence intermediate risk	0.22	Deterministic	[4]
Prevalence of high risk	0.21	Deterministic	
Prevalence of low risk	0.57	Deterministic	[4]
Survival rate with DFU	0.72% on three years	Deterministic	[62]
Survival rate without DFU	0.85% on three years	Deterministic	[62]
Survival rate with amputation	50% on 5 years	Deterministic	[12]
Death rate in LLA with diabetes	4.6 per 100000 in Australia	Deterministic	[4]
Diabetes death in Australia	16.1 deaths per 100,000 people	Consulted on 28 October 2017	[57]
Intervention effectiveness			
Reduction of ulcer	0.31; [RR=0.31, 95%CI: 0.14-0.66]	Lognormal (mean=-1.1, se=0.4)	[23]
Reduction in amputation rate	0.05; [OR=0.05, 95%CI: 0.03-0.08]	Lognormal (mean=-3.09, se=0.10)	[38]
Increased healing rate	1.38; [RR=1.43; 95%CI: 1.11-1.84]	lognormal (mean=0.36, se=0.13)	[14]
Increased early complication detection	1.13; [RR=1.13; 95%CI: 1.00-1.25]	Log normal (mean=0.12, se=0.06)	Assumption
Podiatrist visits, Nurse home dressing-visits, Length of stay in rehabilitation			
No. of podiatrist visits low risk	1	Deterministic	[18]
No. of podiatrist visits intermediate risk	4	Uniform (min=2, max=6)	[18]
No. of podiatrist visits high risk	9	Uniform (min=6, max=12)	[18,34]
No. of podiatrist visits extreme-risk (active ulcer)	36	Uniform (min=24, max=48)	[18,34]
Number of nurse's home visits for dressing	45	Uniform (min=6, max=75)	
Length of stay in rehabilitation	15	Uniform (min=1, max=30)	[61]
Costs items ($)			
Footwear: The cost of footwear in line with the DVA fee schedule at November 2015.	$400	Gamma (mean=800, se=204),)	[44]
Orthotics including negative impression: The cost of custom thermoplastic rigid orthotics in line with the DVA fee schedule at November 2015.	$319	Gamma (420.5, se=52)	[44]
Podiatrist visits: Average costs per half-hour in South Australia public system plus 25% for overhead costs.	$34 [range= 33,35]	Gamma (mean=34, se=0.51)	Market price
Wound dressing	$6 [range=3,15]	Gamma (mean=6, se=3.06)	Market price
TCC/RCW: (online costs for offloading shoes and boots Bledsoe comforter diabetic ulcer walking boots and Aircast XP diabetic walker.	$300	Gamma (mean=500, se=128)	[45,46]
Neuropathy treatment: the cost of pregabalin prescription for pain management is a proxy.	$5,900.90		[43]
Nurse home wound dressing visit	$131	Gamma (mean=131, se=6.63]	Market price
Self-care cost reimbursed by the government: The average cost from the National Diabetes Service Scheme (NDSS) for 2015	$200		[48]
GP Management costs Average benefits paid for the following Medical Benefit Schedule (MBS) items related to allied health services: 10950-70; 81300-60; 81100-25, GP care plan: 721-39; 747; 750; 754; 758, GP attendance items for practice incentive program (PIP): 2517-2526; 2620-35, Health assessment: 701; 703; 705; 707; 715, and Cost of referral when there are co-morbidities: 132; 133.	$1,464		[43]
Wound diagnosis and wound repair Average benefits paid for the following MBS items: 11610-11612; 13020; 30023-30049; and 46414.	$733		[43]

Ulcer infection treatment cost Weighted average by separations for the following AR-DRG items: J64A; J64B; I64A; and I64B, which are related to cellulitis and osteomyelitis [42].	$7,521		
Hospital treatment of infected limb ulcer cost Weighted average by separations for the following AR-DRG items J64A, J64B, I64A, I64B, J12A, J12B and J12C that are related to cellulitis, osteomyelitis and hospital treatment of limb with ulcer	$23,310		[43]
Prostheses	$4,200	Gamma (mean=700, se=765)	[47]
Amputation: Weighted average by separations for the following AR-DRG items: F13A; F13B; and I70Z, which are related to procedures for upper limb and toe amputation for circulatory disorder.	$35,115		[43]
Rehabilitation cost/per day: National efficient price multiplied by the price weight applied for subacute and non acute admission.	$1465	Deterministic	
Quality of life weight per year			
Utility of life without ulcer	0.84		[50]
Utility with history of ulcer or amputation	0.76		[50]
Utility with complication	0.65		[50]
Utility with non-infected ulcer	0.89		[51]
Utility with infected ulcer	0.82		[51]
Utility with amputation	0.58		[51]
(RR: relative risk, OR: odds ratio, max=maximum, min=minimum, se=standard deviation to the mean, CI: confidence interval), LLA: Lower limb amputation, SA: South Australia, TCC/RCW : Total contact casting/Removable cast walker			

Table 1: Clinical data and cost data in the baseline, distribution assumptions and data sources.

	Usual care				Best-evidenced podiatric care			
	Low risk	Intermediate risk	High risk	Active ulcer	Low risk	Intermediate risk	High risk	Active ulcer
Podiatrist foot assessment	-	-	-	-	1	2-6	6-12	24-48
Medical /specialised footwear					-	Yes [4]	yes	yes
Orthoses + negative impression of foot + fitting	-	-	-	yes	-	yes	yes	yes
Total contact casts (TCC) / removable cast walker (RCW)				yes		-	-	yes
Neuropathy treatment (pharmacological) only in diabetes with complications		yes	yes	yes		yes	yes	yes
Wound care				yes				yes
Wound dressing				6-75*				6-75*
Ulcer treatment cost				yes				yes
Prostheses	For active ulcer ending in amputation				For active ulcer ending in amputation			
Amputation costs								
Rehabilitation								

Table 2: Assumptions on the cost items in *Usual* and *Best-evidenced* podiatric care scenarios.

Outcome data

Health-related quality of life values for patients with DM, and those associated with ulcer and amputation, were extracted from the literature [50,51]. These were used in our model to compute quality of life years (QALY). The utility value for health events was derived using a multiplicative formula (e.g. the utility value for a patient with low risk of foot complications and having ulcer is the utility value of low risk multiplied by the utility value of having ulcer). Other outcomes were counts of ulcer, infection and amputation.

Decision-tree modeling

TreeAge Pro 2016 software [52] was used to build a decision-tree model that mapped clinical pathways for the podiatric care of people with DM in usual and best-evidenced podiatric care scenarios (Figure 1). This enabled exploration of the investment required to provide best-evidenced podiatric care to every South Australian with DM, as well as potential downstream savings (in secondary care) if this level of care was available. The costs of care for the South Australian public healthcare budget could then be estimated. Key decision points were identified in the pathways, at which a podiatrist review could address the presence (or absence) of foot-related complications. The decision-tree model mapped the progression of decisions about the level of foot care required, based on the level of risk for South Australians with DM, and estimated the associated costs on the healthcare system. The time frame assumed for the model was five years, with costs calculated in Australian dollars as at 2015. The transition period was one month.

Sensitivity analysis: Multiple one-way sensitivity analyses of incremental effectiveness ratios were conducted and presented in a Tornado plot. A probabilistic sensitivity analysis (PSA) was performed. The probability distributions Uniform, Beta, Gamma, and log-normal were used for the number of podiatrist visits, probability of ulcer infection, costs and relative risk respectively as usually recommended

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in all studies guidelines [53]. A first-order Monte Carlo simulation was conducted, using 100,000 trials and the number of ulcer, infection and amputation were counted.

Results

The usual care and best-evidenced podiatric care model pathways, outlined in Figure 1, were necessarily complex because of the variability with which 'usual care' could be delivered. The pathways were also complicated by the different impacts that usual and best-evidenced podiatric care could have, on avoiding and/ or reducing foot ulcers, infections and amputations. What was clear even when building this model, was that investing in best-evidenced podiatric care for every South Australian with DM would show significant downstream cost-savings in avoided complications.

Cost

The average cost of best-evidence practice podiatric care is $31,424.86, compared with $34,085.72 for usual care. The anticipated investment in best-evidenced podiatric care per patient was estimated as $6.86K in low and intermediate risk patients. This would generate downstream savings in reduced ulcers, infections and amputations of approximately $9.43K per patient for an average net cost-saving of $2.66K per DM patient. In other words, investing $100 in primary and outpatient podiatric care would generate $137 in savings (savings-to-cost ratio=1.37) in terms of outpatient and inpatient hospital services (Figure 2). The expected total net savings from best-evidenced podiatric care would result in savings of $2660 per patient or about $399 million over five years, if the intervention was applied to all people with DM (approximately 150,000 people with diabetes in South Australia) [41].

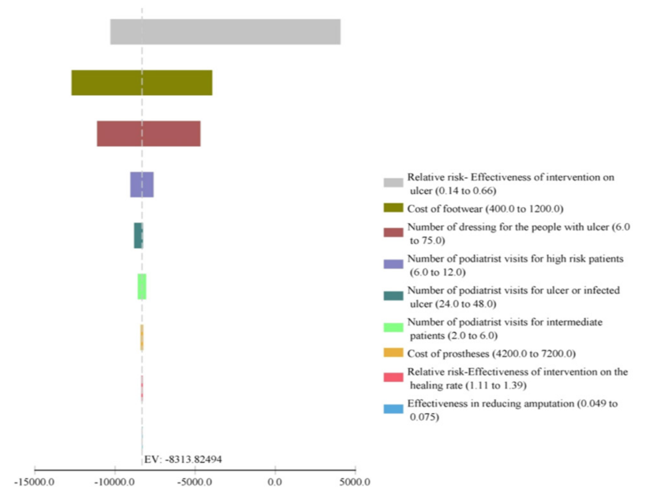


Figure 2: Cost effectiveness of best-evidenced podiatric care over usual care: Multiple one-way sensitivity analysis of incremental effectiveness ratio.

Quality of life

Quality of life for *best-evidenced* podiatric care and *usual care* was 3.33 QALY standard deviation (sd)=0.38) and 3.01 QALY 9 (sd=0.34) respectively.

Multiple one-way sensitivity analysis (Figure 3 Tornado diagram analysis) shows that the results for the cost-effectiveness ratio are highly sensitive to the changes in the capacity of the intervention to reduce ulcer risk. The incremental cost-effectiveness ratio results are moderately sensitive to the modifications in the cost of footwear, and the number of dressings.

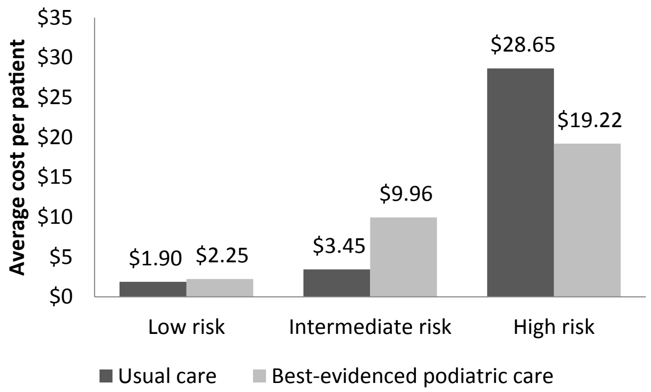
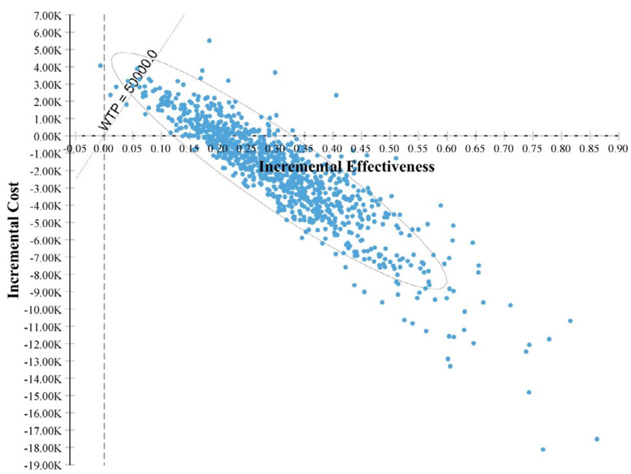


Figure 3: Expected cost per patient per level of risk and care setting ($000).

The first order Monte Carlo simulation with 100,000 trials shows that events of ulcer, infection and amputation were sensitively reduced. In best-evidenced podiatric care, the rates of ulcer, infection and amputation were 1.31844 (sd=1.263), 0.61414 (sd=0.821) and 0.00448 (0.067) respectively. For usual care these rates were 4.72123 (sd=2.411), 2.19742 (sd=1.558) and 0.24306 (sd=0.496) respectively.

The PSA output (Figure 4) suggests that when changing all the variables together in the model, and running the simulation on 100,000 samples, best-evidenced podiatric care was cost-effective compared to usual care in 99% of cases (best-evidenced podiatric care is dominant in 99% of cases and superior-dominant to usual care in 77% of cases) at $50,000/QALY. The average cost of best-evidenced podiatric care was estimated at $32,108.86 (sd=$2,175.89) compared to $34,150.54 (sd=$3,590.36) in usual care. The average net cost-savings is estimated at $2,051.68 per DM patient. The quality of life in best-evidenced podiatric care and usual care was 3.34 QALY (sd=0.11) and 3.01 QALY (sd=0.16) respectively.



WTP: the willingness to pay, Incremental effectiveness incremental QALY

Figure 4: Cost-effectiveness plane: Best-evidenced podiatric care compared to usual care.

Discussion

This research is the first that we know of, to develop and test an economic model to compare best-evidenced podiatric care with usual care for people with DM, in publicly-funded outpatient and community settings, using data from one Australian state (South Australia). The results suggest that provision of best-evidenced podiatric care for every person with DM is associated with significantly-reduced prevalence of avoidable ulcers, infections, hospitalisations and amputations, and that this would produce significant cost-savings in one year in South Australia. Given the increasing prevalence of DM nationally and internationally [1-5], the output of this model suggests that *best-evidenced* podiatric care is essential for all people with DM to avoid lower limb complications from DM, such as avoidable infections, hospitalisations and amputations [8,13-14].

This research only investigated direct healthcare costs associated with the podiatric care pathways outlined in (Figure 1). We did not extend our model past the point of amputation, as the care pathway potentially became more complex. People dealing with amputations require rehabilitation, as well as prostheses, and home and car modifications, and other assistive technologies [42]. Indirect costs (which could include loss of productivity and indirect costs of mental health and family stresses) associated with diabetes lower-limb complications were not considered [12,13]. These costs represent a different perspective of cost estimation which was outside the remit of this research.

There is currently little evidence of the cost effectiveness of any AH intervention for any condition, particularly in downstream prevention of disability, disease and/or death [54,55]. Yet there appears to be untapped opportunities to test whether timely best-evidenced AH interventions for other prevalent chronic conditions can produce downstream cost savings and improved health outcomes [55-62]. Thus, this economic modelling approach developed for podiatric interventions for people with DM could be adapted and applied to other AH interventions for other chronic conditions.

Our model is congruent with the findings of a recent Australian economic study [10], despite different modelling approaches being taken. The Markov model reported by Cheng et al. [10] indicates savings of $2.7 billion in Australia over five years, whilst our study showed savings of $399 million in over five years in one Australian state (South Australia), which has the highest amputation rate in the country. The cost-savings for South Australia generated in our model represent 15% of the Australian savings previously reported [10].

There were significant evidence gaps in the literature, and in '*usual care*' health resource data which constrained our economic modelling exercise. To address these gaps required considerable debate within the research team, and input from experts, prior to agreement being reached on the different pathways of care within the economic model. This highlighted the importance of a multidisciplinary team of researchers, clinicians and policy-makers to address utilisation questions such as this, as well as the need for careful planning, prior to determining and testing any economic model for AH investment in the management of any chronic disease.

During the development of this model, considerable effort was invested in collecting updated representative information (Tables 1 and 2). We contend that the conclusions that were drawn from this study are valid, and the likely bias is small. Thus, although the study focused on South Australian public sector podiatric care provision, we believe the model has worldwide applicability for podiatric care provided in other similar primary care settings.

Conclusion

Best-evidenced podiatric care is cost-saving (savings-to-cost ratio=1.37) in the management and prevention of diabetic foot-related complications in hospital inpatient and outpatient settings in South Australia. It involves ensuring that all people with DM have access to the appropriate level of podiatric care for their individual needs early in their diagnosis. From a policy perspective, best-evidenced GP referral to podiatry, and best-evidenced podiatric care for different risk categories of people with DM offers a significant improvement in quality of life, as well as persuasive cost-saving and cost-effective outcomes, compared to *'usual' care*. From a clinical perspective, a goal of a 50% reduction in amputations in 10 years is achievable and is supported by reports that improvements in diabetic foot care can lead to a 47% to 85% reduction in amputations [2,17,54]. This will ensure better and more consistent best-evidenced management of the diabetic foot, to delay or prevent amputation, and to minimise related costs such as loss of productivity and income, home modifications and indirect costs associated with mental health distress and family stresses.

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This paper draws on data which was provided under a confidentiality agreement with the authors, by the Allied and Scientific Health Office (ASHO), Department of Health and Ageing SA (SA Health). Table 2 provides computed values from this data. All other data applied to the economic models is publicly available and is referenced accordingly. We acknowledge Jeanette Routley, Samantha Kruger and Amy Ross from ASHO, and the SA Health Podiatry Advisory Group, for assistance with data provision, interpretation and commentary, and Maura McInerney and Holly Bowen (iCAHE) for their assistance in editing.

References

1. Ray JA, Valentine WJ, Secnik K, Oglesby AK, Cordony A, et al. (2005) Review of the cost of diabetes complications in Australia, Canada, France, Germany, Italy and Spain. Curr Med Res Opin 21: 1617-1629.
2. Lazzarini PA, Gurr JM, Rogers JR, Schox A, Bergin SM, et al. (2012) Diabetes foot disease: The Cinderella of Australian diabetes management? J Foot Ankle Res 5: 24.
3. King H, Aubert RE, Herman W (1998) Global burden of diabetes 1995-2025: Prevalence, numerical estimates, and projections. Diabetes Care 21: 1414-1431.
4. Australian Institute of Health and Welfare (AIHW) Diabetes Indicator Australia.
5. South Australian Department Health (2009) State-wide Service Strategy Division, Chronic Disease action plan for South Australia. Govt SA, Adelaide.
6. Payne CB (2000) Diabetes-related lower limb amputations in Australia. Med J Aust 173: 352-354.
7. Commission on Safety and Quality in Healthcare Australian atlas of healthcare variations: Interventions for chronic disease. Diabetes-related lower limb amputation hospital admissions 18 years and over. Pp: 329-334.
8. Dillon MP, Fortington LV, Akram M, Erbas B, Kohler F, et al. (2017) Geographic variation of the incidence rate of lower limb amputation in Australia from 2007-2012. Govt SA 12: e0170705.
9. Shaw J, Tanamas S (2012) Diabetes: The silent pandemic and its impact on Australia.
10. Cheng Q, Lazzarini PA, Gibb M, Derhy PH, Kinnear EM, et al. (2016) A Cost-effectiveness analysis of optimal care for diabetic foot ulcers in Australia. Int Wound J 14: 616-628.
11. Australian Institute of Health and Welfare (AIHW) Australia's hospitals 2013-2014 at a glance.
12. Bakker K, Apelqvist J, Lipsky BA, Van Netten JJ, Schaper NC, et al. (2015) On behalf of the International Working Group on the Diabetic Foot (IWGDF) the 2015 IWGDF Guidance documents on prevention and management of foot complications in diabetes: Development of an evidence-based global consensus. Diabetes Metab Res Rev 30: 13-25.
13. Bus SA, van Deursen RW, Armstrong DG, Lewis JEA, Caravaggi CF, et al.

(2015) On behalf of the International Working Group on the Diabetic Foot (IWGDF) (2015) Footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in patients with diabetes: A systematic review. Diabetes Metab Res Rev 32: 99-118.

14. Jeffcoate WJ, Harding KG (2003) Diabetic foot ulcers. The Lancet 361: 1545-1551.

15. Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, et al. (2006) Diabetic foot disorders: A clinical practice guideline (Revision). J Foot Ankle Surg 45: S1-S66.

16. Wrobel JS, Najafi B (2010) Diabetic foot biomechanics and gait dysfunction. J Diabetes Sci Technol 4:833-845.

17. Van Schie CM (2005) A review of the biomechanics of the diabetic foot. Int J Low Extrem Wounds 4: 160-170.

18. National Health & Medical Research Council (NHMRC) (2011) National evidence-based guideline for the prevention, identification and management of foot complications in diabetes (part of the guidelines on type 2 diabetes).

19. Boulton AJM, Armstrong DG, Albert SF, Frykberg RG, Hellman R, et al. (2008) 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 31: 1679-1685.

20. Markakis K, Bowling FL, Boulton AJ (2016) The diabetic foot in 2015: An overview. Diabetes Metab Res Rev 32: 169-178.

21. Lavery LA, Davis KE, Berriman SJ, Braun L, Nichols A, et al (2016) WHS guidelines update: Diabetic foot ulcer treatment guidelines. Wound Rep Reg 24: 112-126.

22. Ogrin R, Forgione N (2016) Prevention, screening and referral of people with diabetes-related foot complications in primary care. J Prim Care 1: 86-93.

23. Wu SC, Driver VR, Wrobel JS, Armstrong DG (2007) Foot ulcers in the diabetic patient, prevention and treatment. Vasc *Health* Risk Manag 3: 65-76.

24. Van Netten JJ, Price PE, Lavery LA, Monteiro-Soares M, Rasmussen A, et al. (2016) On behalf of the International Working Group on the Diabetic Foot (IWGDF). Prevention of foot ulcers in the at-risk patient with diabetes: A systematic review. Diabetes Metab Res Rev 32: 84-98.

25. Scharper NC, Van Netten JJ, Apelqvist J, Lipsky BA, Bakker K et al. (2017) Prevention and management of foot problems in diabetes: A Summary Guidance for Daily Practice 2015, based on the IWGDF guidance documents. Diabetes Res Clin Pract 124: 84-92.

26. Elraiyah T, Tsapas A, Prutsky G, Domecq JP, Hasan R, et al. (2016) A systematic review and meta-analysis of adjunctive therapies in diabetic foot ulcers. J Vasc Surg 63: 46S-58S.

27. Australian Government Department of Health (2016) Medicare Benefits Schedule Book.

28. Australian Institute of Health and Welfare (AIHW). Annual cycle of care.

29. Quinlivan E, Jones S, Causby R, Brown D (2014) Reduction of amputation rates in multidisciplinary foot clinics - A systematic review. Wound Practice and Research 22: 155-165.

30. Bakker K, Apelqvist J, Schaper NC (2012) On behalf of the International Working Group on the Diabetic Foot Editorial Board. Practical guidelines on the management and prevention of the diabetic foot. Diabetes Metab Res Rev 28: 225-231.

31. Boulton AJM, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J (2005) The global burden of diabetic foot disease. The Lancet 366: 1719-1724.

32. Bergin SM, Gurr JM, Allard BP, Holland EL, Horsley MW, et al. (2012) Australian Diabetes Foot Network: Management of diabetes-related foot ulceration: a clinical update. Med J Aust 197: 226-229.

33. Wounds International. International best practice guidelines: Wound management in diabetic foot ulcers.

34. Edwards J, Stapley S (2010) Debridement of diabetic foot ulcers. Cochrane Database of Systematic Reviews.

35. Fisher TK, Scimeca CL, Bharara M, Mills JM Sr, Armstrong DG, et al. (2010) A step-wise approach for surgical management of diabetic foot infections. J Am Podiatr Med Assoc 100: 401-405.

36. Woo KY, Botros M, Kuhnke J, Evans R, Alavi A, et al. (2013) Best practices for the management of foot ulcers in people with diabetes. Adv Skin Wound Care 26: 512-523.

37. Ragnarson-Tennvall G, Apelqvist J (2001) Prevention of diabetes-related foot ulcers and amputations: A cost-utility analysis based on Markov model simulations. Diabetologia 44: 2077-2087.

38. Rice JB, Desai U, Cummings AKG, Birnbaum HG, Skornicki M, et al. (2014) Burden of diabetic foot ulcers for Medicare and private insurers. Diabetes Care 37: 651-658.

39. Carls GS, Gibson TB, Driver VR, Wrobel JR, Garoufalis MG, et al. (2011) The economic value of specialised lower-extremity medical care by podiatric physicians in the treatment of diabetic foot ulcers. J Am Podiatr Med Assoc 101: 98-115.

40. Rogers LC, Lavery LA, Armstrong DG (2008) The right to bear legs - An amendment to healthcare: How preventing amputations can save billions for the US health-care system. J Am Podiatr Med Assoc 98: 166-168.

41. Trends at a Glance: Diabetes trends in South Australia adults July 2002 to December 2015.

42. Stare J, Maucort-Boulch D (2016) Odds Ratio, Hazard Ratio and Relative Risk, Metodoloski Zvezki. 13: 59.

43. Department of Human Services. Medicare Item Reports.

44. Department of Veterans' Affairs (DVA). Podiatrists schedule of fees effective of November 2015.

45. Better Braces. Online Shopping Portal.

46. Reduto. Online Shopping Portal.

47. Noonan M. Limbs 4 life Productivity commission submission inquiry into disability care and support.

48. National Diabetes Services Scheme (NDSS). Snapshot diabetes data 2016.

49. Ortegon MM, Redekop WK, Niessen LW (2004) Cost-effectiveness of prevention and treatment of the diabetic foot. Diabetes Care 27: 901-907.

50. Clarke PM, Hayes AJ, Glaziou PG, Scott R, Simes J, et al. (2009) Using the EQ-5D index score as a predictor of outcomes in patients with type 2 diabetes. Medical Care 47: 61-68.

51. Redekop WK, Stolk EA, Kok E, Lovas K, Kalo Z, et al. (2004) Diabetic foot ulcers and amputations: estimates of health utility for use in cost-effectiveness analyses of new treatments. Diabetes Metab 30:549-556.

52. TreeAge Software, Inc. TreeAge Pro 2016 R1.0, TreeAge software. Williamstown, MA.

53. Briggs AH, Weinstein MC, Fenwick EAL, Karnon J, Sculpher MJ, et al. (2012) On behalf of the ISPOR-SMDM Model Good Research Practices Task Force, Model parameter estimation and uncertainty: A report of the ISPOR-SMDM Modeling Good Research Practices Task Force-6. Value Health 15: 835-842.

54. Lopez-de-Andres A, Jimenez-Garcia R, Aragon-Sanchex J, Jimenez-Trujillo I, Hernandez-Barrera V, et al. (2015) National trends in incidence and outcomes in lower extremity amputations in people with and without diabetes in Spain, 2001-2012. Diabetes Res Clin Pract 108: 499-507.

55. Phillips C. Allied health: The untapped potential in the Australian health system. The Health Advocate 2015.

56. Farag I, Sherrington C, Ferreira M, Howard K (2013) A systematic review of the unit costs of allied health and community services used by older people in Australia. BMC Health Serv Res 13: 69.

57. Boyko EJ, Ahroni JH, Cohen V, Nelson KM, Heargerty PJ, et al. (2006) Prediction of diabetic foot ulcer occurence using commonly available clinical information: The Seattle diabetic foot study. Diabetes Care 29: 1202-1207.

58. Milne TE, Schoen DE, Bower VM, Burrows SA, Westphal C, et al. (2013) Healing Times of Diabetic Foot Ulcers: Investigating the Influence of Infection and Peripheral Arterial Disease. Diabet Complications 51: 29-38.

59. Rodrigues BT, Vangaveti VN, Malabu UH (2016) Prevalence and risk factors for diabetic lower limb amputation: A clinic-based case control study. J Diabetes Res 16: 1-7.

60. Ramsey SD, Newton K, Blough D, McCulloch DK, Sandhu N, et al. (1999) Incidence, outcomes, and cost of foot ulcers in patients with diabetes. Diabetes Care 22: 382-387.

61. Hordacre BG, Stevermuer T, Simmonds F, Crotty M, Eagar K, et al. (2013) Lower-limb amputee rehabilitation in Australia: Analysis of a national data set 2004-2010. Aust Health Rev 37: 41.

62. Standardised death rates for DiabetesZV (E10-E14) in Australia, 2006-2015 (a,b)-Diabetes SDRs by sex, 2006-2015.