Griffith UNIVERSITY
Centre for Applied Health Economics

Queensland Government

AN ECONOMIC EVALUATION OF A NOVEL FUNDING MODEL FOR DIABETIC FOOT DISEASE

FINDINGS REPORT

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EXECUTIVE SUMMARY

BACKGROUND

Diabetes-related foot disease (DFD) is now a leading cause of hospitalisation, disability and amputation burden in Queensland, Australia and globally [1-7]. Previous economic evaluation analyses have reported that significant cost reductions are achievable when using best practice DFD care.

In 2018, the Queensland Department of Health announced a $AU17.5 million policy initiative to improve access to ambulatory DFD services for people with DFD across the state of Queensland (Australia). The new funding initiative (referred to as the Diabetes-related Foot Disease Service (DFDS) for the purpose of this study) was designed to incentivise improved DFD service models aligned with research [6-13] and recommendations made in national and international guidelines [14-19]. Unlike traditional funding models used in Australian public hospitals that provides funding based on service delivery, funding was tied to meeting key performance targets. Specifically, each Hospital and Health Service (HHS) that accepted funding provided a formal commitment to meet: 1) >80% of patients with a referral for a new DFD episode assessed and a care plan initiated within two working days from receipt of a referral, and 2) total DFD patient visits per month will be equivalent to a minimum penetration of 30% of the estimated target service population with DFD. Importantly, all HHSs retained autonomy with regards to the specific nature and type of activities they undertook to meet the targets.

An economic evaluation was undertaken to determine whether the newly funded DFDS model is cost-effective compared to the current DFD service model funded based on activity. A cost effectiveness analysis (CEA) was applied to determine the extent to which this large regional investment represents value for money and the return on investment (ROI) of the additional novel funding. However, whilst intermediate outcomes could be observed relatively quickly after the implementation of the novel funding model, the full costs and health consequences are likely to be realised over the life of each patient treated. To account for the full costs and benefits of implementing the strategy, and thereby estimate the ROI, an assessment of the relationship between intermediate outcomes (such as time to remission of DFD; time to recurrence and frequency of recurrence) and longer-term outcomes (such as hospitalisation, amputation, and mortality) was conducted.

This evaluation utilised routinely collected clinical outcome data before and after the introduction of the new funding model along with patient reported health-related quality-of-life (HRQoL) data to develop an economic model. The model was used to extrapolate from observed differences in intermediate outcomes and estimate the impact on long-term health and costs. To our knowledge, no studies have previously investigated the cost-effectiveness of implementing an outcome-linked funding strategy to support best practice DFD service models at a population level.

STUDY DETAILS

A retrospective data-linkage cohort study was applied to compare costs and outcomes of 3,821 DFD patients in the usual care group and 4,432 patients in the DFDS group (total n=8,253). The main data source included routine outpatient clinical data collected from the Queensland High-Risk Foot Database. The usual care group were defined as patients with

clinical visits between July 2015 and June 2019 while the DFDS group were defined as those with clinical visits between July 2019 and November 2020. This data set was then linked with the Queensland Hospital Admitted Patient Data Collection (QHAPDC), National Hospital Costs Data Collection (NHCDC) and the Death Record Registration. Costs associated with usual care were adopted from a previous study [20] while costs of the DFDS was estimated using the total DFDS funding and the number of clinical visits in the study period.

A Bayesian multi-state Markov model was used to estimate the transition probabilities for usual care and DFDS groups. Monte-Carlo simulation was then used to examine the robustness of cost-effectiveness findings and assess the uncertainty in the results (Figure 1). Transition probabilities were estimated in an unrestricted fashion and as such, for example, a patient can proceed from a major amputation to hospitalisation and then go on to have another major amputation.

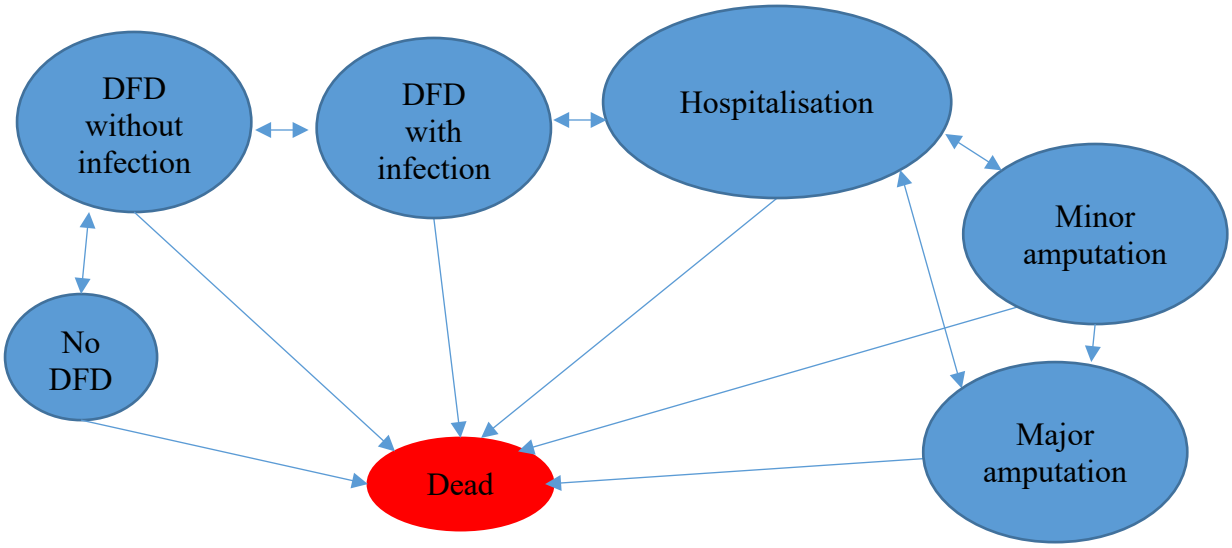

Figure 1. The progression of diabetes-related foot disease (DFD)

RESULTS

Following the introduction of the DFDS, the probability of hospitalisation reduced from 29.2% to 23.5%, while the respective figures for minor amputations were 8.6% and 6.5%. In addition, hospital length of stay was significantly less for the DFDS group at 7.5 days compared to 8.9 days for the usual care group.

We found that the DFDS was cost-effective compared to the usual care model. The main driver of cost savings was the lowered probability of hospitalisation, as well as minor and major amputations, which have a substantially higher unit cost compared to that of general clinical foot services. On average, one dollar invested in the DFDS was associated with a return of $7.72 ($6.46 if value of QALY gained was excluded). The probabilistic sensitivity analysis identified that the DFDS has a 93.53% chance of being cost-effective (Figure 2).

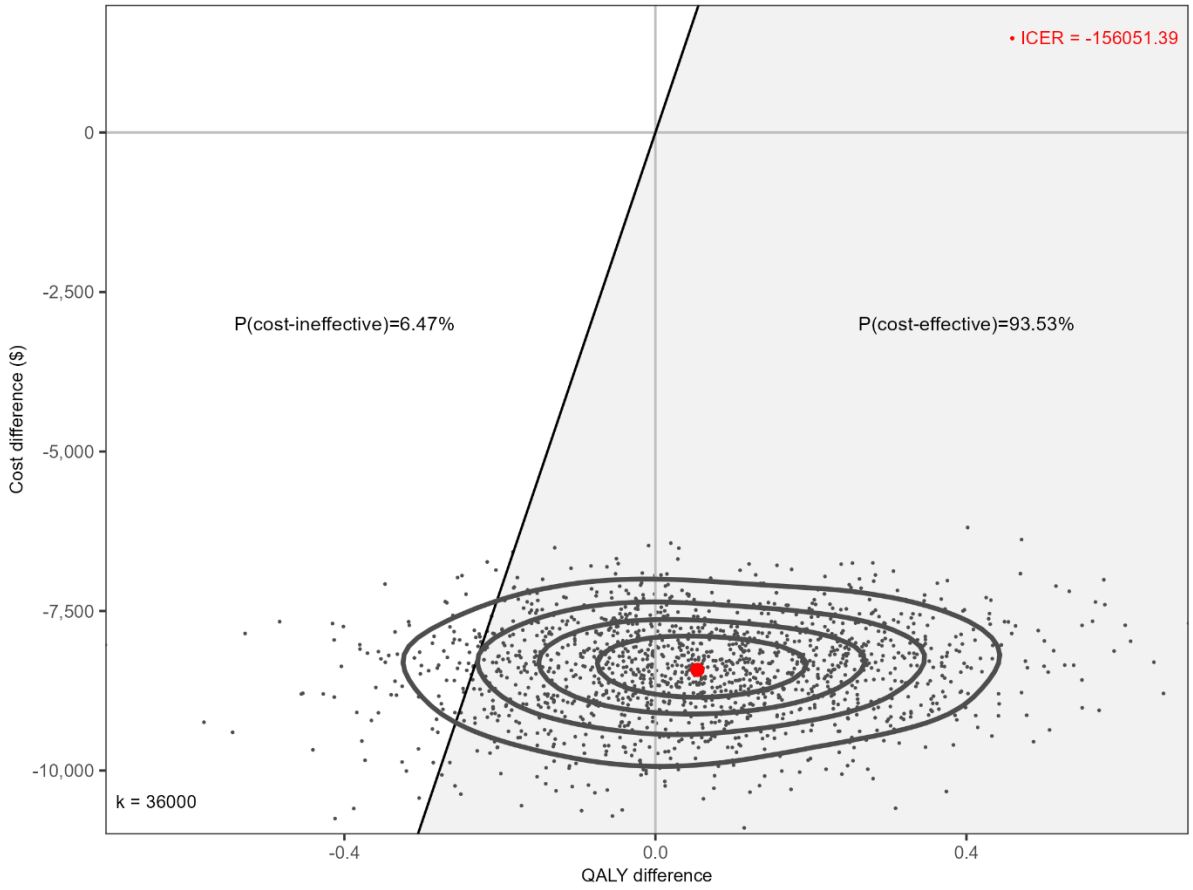

Figure 2. Probabilistic Sensitivity Analysis

The confirmation of a reduction in DFD hospitalisations and subsequent cost-savings achieved with the implementation of the novel DFDS represents a high return on investment.

1 BACKGROUND

Diabetic foot disease (DFD), which will affect approximately 19% to 34% of persons with diabetes, is a leading cause of hospitalisations, amputations, and disability burden in Australia and globally [1, 10, 21]. DFD is defined as infection, ulceration, or destruction of tissues of the foot of a person with currently or previously diagnosed diabetes mellitus, usually accompanied by neuropathy and/or peripheral artery disease (PAD) in the lower extremity [22]. The substantial portion of the economic burden associated with DFD is avoidable. The direct cost of DFD to the Australian health system was estimated at $1.6 billion in 2015 [2]. The cost of hospitalisations alone was $348 million [7], with over 65% of all diabetic patients admitted to hospital presenting with at least one prior foot complication and over 38% with multiple prior presentations for foot complications [23]. Previous research has demonstrated that this substantive burden can be significantly reduced with improved access to, and quality of, multi-disciplinary ambulatory DFD care [6-13].

The Queensland Department of Health has recently provided a new recurrent funding initiative to improve access to ambulatory DFD services for people with DFD across the state of Queensland (Australia). The new funding initiative, titled the Diabetes-related Foot Disease Service (DFDS) for the purpose of this study, was designed to incentivise improved DFD service models aligned with research [6-13] and recommendations made in national and international guidelines [14-19]. It is anticipated that the recurrent funding, commencing with $3.28 million in 2018/19 and scaled up to $4.74 million per year from 2019/20, will create sustainable evidence-based service models within each Hospital and Health Service (HHS) that meet set key performance indicators (KPI) and in turn, result in a reduction in hospitalisation and amputation rates.

Funding for this new initiative is linked to treatment timeliness and total DFD patient throughput targets in ambulatory DFD care that reflect Australian best practices in preventing DFD-related hospitalisation, disability and amputation [7, 19]. Each HHS that accepted funding provided a formal commitment to meeting KPIs whereby 1) >80% of patients with a referral for a new DFD episode will be assessed and a care plan initiated within two working days from receipt of a referral, and 2) total DFD patient visits per month will be equivalent to a minimum penetration of 30% of the estimated target service population with DFD in all HHSs. All HHSs have autonomy with regards to the specific nature and type of activities they implement to achieve KPIs. If the HHS accepts funding and does not meet the agreed KPIs as agreed and set out in the HHS service agreement, the Queensland Department of Health has the ability to withdraw the additional HHS funding for the new service (funding above the usual activity-based funding), as a last resort.

To determine whether the newly funded DFDS model can demonstrate value it is imperative to undertake an economic evaluation to compare against the previous DFDS model funded based on activity. The economic evaluation was applied to determine the extent to which this large regional investment represents value for money and the ROI of the additional novel funding. However, whilst intermediate outcomes could be observed relatively quickly after implementation of the novel funding model, the full costs and health consequences are likely to be realised over the life of each patient treated. To account for the full costs and benefits of implementing the strategy, and thereby estimate the ROI, an assessment of the relationship between intermediate outcomes (such as time to remission of DFD; time to recurrence and frequency of recurrence) and longer-term outcomes (such as hospitalisation, amputation, and mortality) is necessitated.

Previous cost-effectiveness analyses of such best practice DFD care compared to usual care have reported that significant cost reductions are possible. However, these analyses have typically used models incorporating findings from historical international studies, expert opinions, and strict assumptions [20, 24, 25]. In particular, assumptions are used in economic models regarding the probability of infection healing, the efficacy of change in practice on healing rates, the probability of death within this patient cohort, the increased risk of mortality associated with DFD, the reduction in risk of mortality associated with healing an episode of DFD, an equivalent probability of death among those with an amputation and those with a current DFD, the cost of hospital and health services and the health-related quality of life among those with a current DFD, those with a healed DFD, those with an amputation. These strict assumptions were used for various reasons such as the lack of primary data to estimate transition probabilities among health states. With the availability of patient-level data some of these assumptions can be resolved based on evidence.

2 EVALUATION DESIGN

An economic evaluation, specifically a cost effectiveness analysis (CEA), was required to examine whether the newly funded DFDS model is cost-effective compared to the current DFDS model funded based on activity. This evaluation utilises clinical outcome and quality of life data inputs to develop an economic model to extrapolate from observed differences in intermediate outcomes and estimate the impact on long-term health and costs. To our knowledge, no studies have investigated the cost-effectiveness of implementing an outcome-linked funding strategy to support best practice DFD service models at a population level.

Ethical approval for this study was obtained from the Human Research Ethics Committee (HREC) for Prince Charles Hospital, Metro North Hospital and Health Service (HREC/2020/QPCH/64051), with reciprocal ethical approval obtained from the Griffith University HREC (2020/492). Site-specific authority approvals were also obtained from each of the participating sites. As it was not possible to obtain individual consent for use of evaluation related hospital admission and DFD clinical data for the entire evaluation cohort, a Public Health Act (PHA 64051.1) approval was obtained.

2.1 AIM

The primary aim of this evaluation was to examine the cost-effectiveness of an additional novel funding model (DFDS) for people with DFD across Queensland compared to the current activity-based funding model of DFD services.

2.2 METHODS

2.2.1 POPULATION

The evaluation collected data for all Queenslanders that had consulted a Queensland DFD service capturing routine outpatient clinical data that is held by the Queensland High-Risk Foot Database (QHRFD), Clinical Access and Redesign Unit, Queensland Health – CARU) for the first clinical visit between July 2015 and June 2019 (pre-implementation) and July 2019 and November 2020 (post-implementation). The first clinical visit was defined as the first date the patient attended the DFD service in either of those periods. If data were missing for a variable, the second visit's data was used for that variable(s) if available, provided the second visit was within one month of the first visit. A patient may have attended the service prior to July 2015; however, this data was not captured for this evaluation.

2.2.2 VARIABLES & DATA SOURCES

DFD and infection status were identified through the relevant field in the QHRFD data set. Diabetes foot-related hospitalisations were defined as having diabetes and a foot-related complication diagnosed and entered in the hospital medical record by a physician during the hospital separation and subsequently coded and entered into the admission records by professional coders [26]. Amputation cases were defined as any lower extremity amputation procedural code identified within the identified foot-related hospital admissions. Major amputations were defined as all procedural codes for lower extremity amputation procedures through or proximal to the ankle, and minor amputations were defined as amputation procedures distal to the ankle. In admissions with multiple amputation procedure codes for the same admission separation, the highest level of amputation was assigned as the single amputation procedure for that admission only (Appendix A). Variables included in the analysis and their data sources are described below.

PARTICIPANT CHARACTERISTICS

The following variables were collected from the QHRFD:

a) *Demographics*: age, sex, Indigenous status, hospital and health service name;
b) *Diabetes history*: diabetes type, diabetes duration, HbA1c;
c) *Medical history*: comorbidity type (i.e. history of neuropathy, hypertension, dyslipidaemia, cardiovascular disease (CVD), End-Stage Renal Failure (ESRF), peripheral artery disease (PAD), smoking status, CKD), and count Charlson Comorbidity index;
d) *Foot disease history*: previous amputation, previous hospitalisations for foot disease;
e) *Process measures:* date of referral, date of initial DFDS visit;
f) *Foot risk factors:* peripheral neuropathy, PAD severity, foot deformity;
g) *Active foot disease:* suspected acute Charcot foot, ulcer surface area (mm^2), ulcer grade and depth according to University of Texas Diabetic Wound Classification System, infection severity;
h) *Treatment provided:* irremovable offloading device, appropriate footwear, antibiotics required; health professionals attending.

HEALTH STATES

The following variables were collected from several routinely-collected databases to capture each health state:

a) *No DFD* (Previously healed DFD), identified from:
    - "Previously healed foot ulcer", "Current foot ulcer", and "Combined surface area / Outcome" items from the QHRFD;
b) *DFD without infection*, identified from:
    - "Current foot ulcer" and "Infection (status)";
c) *DFD with infection*, identified from:
    - "Current foot ulcer" and "Infection (status)" (mild, moderate or systemic);
d) *Hospitalisation*, for DFD-related treatment[1] collected from:
    - the Queensland Hospital Admitted Patient Data Collection (QHAPDC)
e) *Minor amputation*, identified from QHRFD items:

- "Previous amputation", "current amputation" and linked with previous QHAPDC diagnosis and procedure codes to confirm minor amputation;

f) *Major amputation*, identified from QHRFD items:
   - "Previous amputation", "current amputation" and linked with previous QHAPDC diagnosis and procedure codes to confirm major amputation; and

g) *Death* (Mortality) collected from the Registrar General Deaths (RGD) database.

Since the focus of this study was on the impact of care provided at the DFD service (pre and post implementation of the new funding model),we excluded hospital admissions before the first visit to the service. The linked data showed that hospital costs were not available for the intervention period. Thus, we assumed that the average cost of hospitalisation remained the same after the new DFDS was introduced on 30 June 2019.

HEALTH RELATED QUALITY OF LIFE (HRQOL)

To enable the calculation of Quality Adjusted Life Years (QALYs), Health Related Quality of Life (HRQoL) data and self-reported disease status was collected through administration of the EQ-5D:5L survey to a sub-cohort of identified patients. Survey data was linked to the above data variables using individual as well as event identifiers. Further details of the methods used to collect HRQoL data is included in Appendix B.

2.2.3 ANALYSES

This study evaluated the cost-effectiveness of the DFDS initiative compared to routine care using a cost-effectiveness analysis, conducted from a health system perspective.

PROGRESSION OF HEALTH STATES

A Bayesian Markov model [27] was employed to examine the progression of DFD during the pre-intervention (i.e., prior to the introduction of the new DFD service) and post-intervention periods. In this model, patients progress through the seven health states with relationships depicted in Figure 1 below.

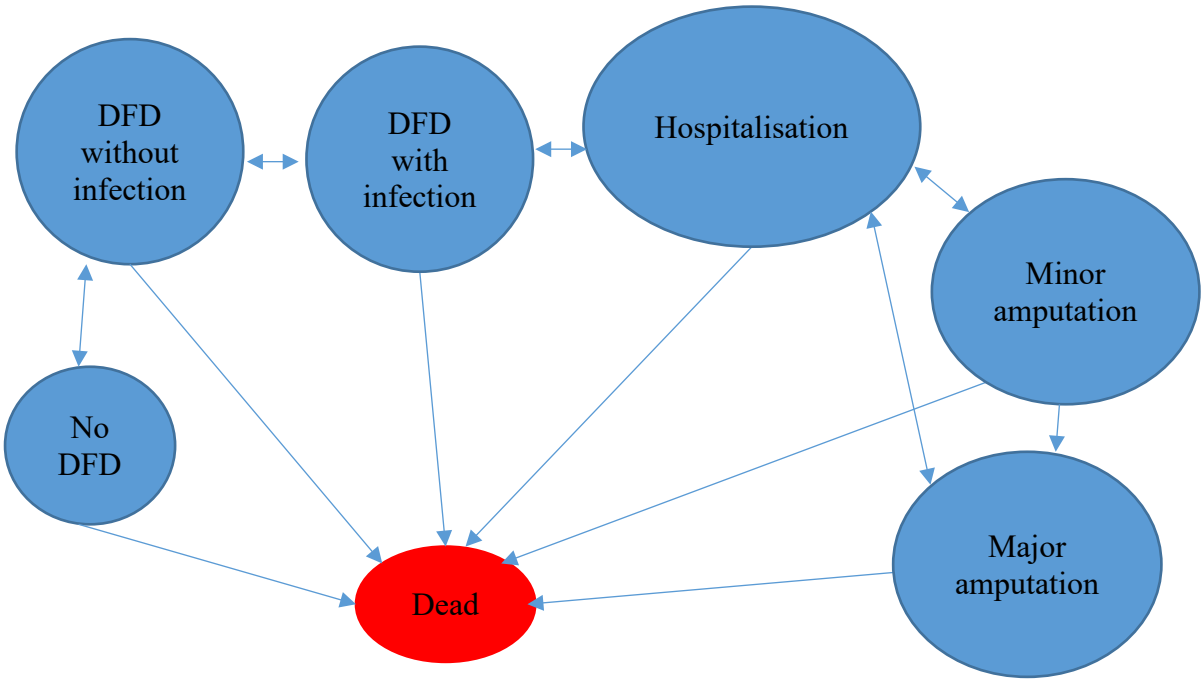

Figure 3. The progression of Diabetes Related Foot Disease (DFD)

Apart from the absorbing state (death), patients can move back and forth from one state to the next state in the sequence or remain in the current state. Assuming that the state transition occurs in discrete time (i.e., cycle), the transition probabilities at time *t* is represented as $P_t = e^{tQ}$ where Q is the transition rate matrix. Each component of the Q matrix represents changes in transition probabilities for small amount of time into the future. The transition probability matrix is estimated from the observed data. When the length of the observed periods (i.e., pre-DFDS and post-DFDS) differ from the cycle length, we apply an Eigenvalue decomposition approach to convert the transition matrix to the selected cycle length[28]. First, the transition rate matrix Q is estimated by taking the matrix logarithm of the observed transition matrix: $Q = \ln(P) = A.\ln(D).A^{-1}$ where *A* is the matrix consist of Eigenvectors of *P*, and *D* is the vector of diagonal elements of *P*. This approach can only be applied when the observed matrix P can be diagnosed. In addition, regularisation could be applied to ensure that Q is an intensity matrix (i.e., each row sums to zero). The conversion of the P matrix to desirable cycle length was conducted through the transition rate matrix Q. Particularly, if the observed period consisted of *n* desirable cycles, the converted transition matrix was $P_n = e^{Q/n}$.

The probabilities of each health state at period *t* are represented by the vector π_t=(π_{t1}, π_{t2} ... π_{tS}) where *S* is the number of health states. For each cycle *t>1*, there exists a recursive relationship of transition probability vector that $\pi_t = \pi_{t-1}P_t$. For comparison with previous studies[20, 29], we selected a monthly cycle with a total duration of 60 cycles (5 years) to simulate costs and outcomes. Likewise, the vector *m,* representing the number of cases in different health states, follows a recursive relationship: $m_t = m_{t-1}P_t$.

The transition matrix *P* was estimated using a Bayesian framework. Particularly, the transition probability vector *p* moving from state *s* to other health states at period *t* were estimated using a multinomial distribution as $r_s^t|p_s^t \sim Multinomial(p_s^t, n_s^t)$ where *r* represents the number of observed individuals, *n* represents the sample size (number of iterations in a simulation), and the vector p_s is summed to one. A prior for vector p_s is modelled using a Dirichlet distribution $p_s^t|\alpha_s^t \sim Dirichlet(\alpha_1^t, \alpha_2^t, \dots, \alpha_S^t)$ where *S* is the number of health states, and α_s represents a vector of hyper-parameters.

Except for the absorbing death state, transition probabilities from the remaining six health states were modelled using 10,000 iterations with the burn-in rate of 5000 (i.e., the first 5000 observations were discarded) and a thinning ratio of 10 (i.e., save one in every ten iterations) and three Markov chains. Thus, 1500 iterations were used to generate statistical properties (e.g., means and 95% confidence intervals) of transition probabilities. The estimated parameters are assessed using potential scale reduction, representing the squared root of the posterior variance and within-chain variance ($\hat{R}$). As a rule of thumb, $\hat{R} \leq 1.1$ indicates good convergence as there are little differences between posterior variance (i.e., a weighted sum of within-chain and between-chain variance) and the variance within a Markov chain [27, pp.67-68].

QUALITY ADJUSTED LIFE YEARS (QALYS)

Quality Adjusted Life Years (QALYs) combine morbidity and mortality as a summary health outcome and was estimated for both the intervention and comparator. QALYs were estimated for both intervention and comparators as:

$$QALY = \sum_{t=a}^{a+L} \frac{Q_t}{(1+r)^{t-a}}$$

Where:
QALY = quality adjusted life years
a = current age
L = life expectancy or model duration
t = time period within that life expectancy/model duration
Q = vector of health-related quality of life weights for each time period
r = discount rate

HRQoL weights, Q, were informed by EQ-5D:5L survey data. HRQoL data analysis details are included in Appendix A. Secondary health outcome measures for both the intervention and comparator were also accrued as part of the model outputs, including the expected number of amputations, foot-related hospitalisations, and life-years.

COSTS
The analysis considered both the cost of the intervention, funding provided as part of the novel funding model, as well as cost consequences with respect to HHS utilisation.

Costs for both intervention and comparator were estimated as:

$$Total\ Cost = \sum_{t=a}^{a+L} \frac{Cost_t}{(1+r)^{t-a}}$$

Where:
Cost = health care cost incurred in period
a = current age
L = life expectancy or model duration
t = time period within that life expectancy/model duration
r = discount rate

COST AND QUALITY OF LIFE INPUT PARAMETERS
In this study, QALY weights for non-fatal health states (no DFD, DFD without infection, DFD with infection, hospitalisation, minor amputation, and major amputation) were 0.573, 0.554, 0.452, 0.532, 0.54, -0.12, respectively. The death state was associated with zero QALY. Note that QALY of major amputation was considered worse than death. Since the monthly cycle is larger than the average length of stay of hospitalisation (i.e., eight days), the QALY weight for this health state was estimated as the weighted sum of QALY for hospitalisation state for eight days and the healthy state (i.e., no DFD) for the remaining time of the month. The unit costs of being in the first three health states, associated with foot clinic services, for usual care models were obtained from Cheng et al.[20] and converted to 2021 price using the Australian consumer price index[30]. The unit price for the DFDS period was calculated as the price of the usual care period and the total DFDS investment of $4,736,083 ($3,266,349 for the financial year 2018-2019, and $1,469,734 for the financial year 2019-2020), and divided by the total number of DFDS visits during the intervention period. It is assumed that the health state of no DFD incurred no cost. The costs for DFD without and with infections were $349.2 and $364.4 for the usual care model and $1,114.5 and $1,163.0

for the DFDS model. It is assumed that the DFDS had no effect on per separation hospital costs; the estimated average costs associated with hospitalisation, minor amputation and major amputation using observed data were $11,410, $22,956.9 and $55,538.4, respectively.

Analysis
The costs and outcomes (e.g., Quality-Adjusted Life Years- QALY) associated with each health state was multiplied by the number of individuals in each state and then summed over study cycles to obtain the aggregate costs and outcomes.

Costs and QALYs were also discounted when the time horizon of analysis was more than one year. The estimation of costs and outcomes was conducted for both control (i.e., pre-implementation period) and treatment (i.e., post-implementation period) so that economic evaluation indicators such as incremental cost-effectiveness ratio (ICER) and ROI could be estimated. A discount at a rate of 5% per annum in line with standard practices for health economic evaluation [31] was applied. Subsequent sensitivity analyses explored alternative discount rates.

ECONOMIC EVALUATION MEASURES
Two main measures of economic evaluation in this study include the ICER and returns on investment (ROI).

Incremental Cost-Effectiveness Ratio (ICER)
The ICER was calculated to determine whether the new funding model was 'good value for money'. The ICER is defined as:

$$ICER = \frac{Total\ Cost_i - Total\ Cost_{uc}}{QALY_i - QALY_{uc}}$$

Where:
Total $Cost_i$ = Total cost for intervention
Total $Cost_{uc}$ = Total cost for usual care
$QALY_i$ = Quality-adjusted life years for intervention
$QALY_{uc}$ = Quality-adjusted life years for usual care

An intervention is considered 'good value for money' when the ICER falls below the decision maker's maximum willingness to pay for health benefits, in the case a QALY. The decision rule by: $\Delta Cost/\Delta QALY$(ICER) <λ, where λ is the decision maker's opportunity cost value of health benefits (QALY). For this analysis, a λ of $36,000 per QALY was used based on recently published estimates for Australia [29]. Subsequent sensitivity analyses explored alternative values for λ including those derived using alternative approaches.

Return on Investment (ROI)
Due to potential identified difficulties associated with interpretation of ratios (i.e. a negative ICER may indicate either an intervention is less costly and more effective or more costly and less effective) as well as usefulness to decision-makers whereas the difference in cost or difference in QALY approaches 0; a net monetary benefit and return on investment approach will also be applied to aid interpretation. The net monetary benefit of an intervention is specified as: $\Delta Cost - \Delta QALY \times \lambda$. Where a net monetary benefit of greater than 0 is considered good value for money. With respect to return on investment, direct incremental

costs of the intervention ($Cost_{inv}$) are separated from the incremental cost consequences ($Cost_{con}$) associated having made the intervention. More formally,

$$ROI = \frac{\left(Cost_{con} + (\Delta QALY \text{ x } \lambda)\right) - Cost_{inv}}{Cost_{inv}}$$

where:
$Cost_{con}$ = incremental difference in the net present value of cost consequences between intervention and comparator
$Cost_{inv}$ = incremental difference in cost between delivering intervention and comparator

CHARACTERISING UNCERTAINTY
A probabilistic sensitivity analysis was conducted to estimate the 95% credible interval for the summary economic outcome measures using Monte Carlo simulation. Random re-sampling of model inputs (including transition probabilities, cost, and utility values) will be simulated 1500 times, which is the number of observations saved from the Markov chain simulation to estimate the transition probability matrix.

3 FINDINGS

3.1 DESCRIPTIVE STATISTICS

A total of 8,253 individuals (3,821 in usual care group and 4,432 in DFDS group) were included in the evaluation. The descriptive statistics (Table 1) show that there were no significant differences in patient characteristics between the two models of care (usual care vs DFDS), except for age. The majority of participants in both the usual care and DFDS groups were non-indigenous (84.1% and 84.2% respectively) males (69.5% and 70.4% respectively). With regards to DFD characteristics, most of the participants risk of DFD in both groups were classified as acute (86.1% usual care vs 89.9% DFDS) and were classified in Health State 2: *DFD without infection* (35.5% and 40.2% respectively).

The unadjusted analysis found some significant differences in outcomes in the period post-introduction of the novel funding for the DFDS (Table 2). The duration of time from the point of referral to the first clinic visit which reduced from 6 days to 5.5 days and the average length of stay (LOS) in hospital reduced from 8.9 days to 7.5 days. The probability of hospitalisation reduced from 29.2% to 23.5%, and the probability of a minor amputation reduced from 8.6% to 6.5% between the pre and post implementation periods of the novel funding for DFDS. The probability of major amputation reduced from 1.0 to 0.7%, however this reduction was not statistically significant. The probability of having no infection also increased slightly from 35.5% to 40.2%.

Table 1. Descriptive statistics

	Usual care (N=3821)	DFDS (N=4432)	Total (N=8253)	p-val.
Participant Characteristics				
Sex*:* n (%)				0.383
Female	1164 (30.5)	1311 (29.6)	2475 (30.0)	
Male	2657 (69.5)	3121 (70.4)	5778 (70.0)	
Indigenous status: n (%)				0.887
Non-indigenous	3214 (84.1)	3733 (84.2)	6947 (84.2)	
Indigenous	607 (15.9)	699 (15.8)	1306 (15.8)	
Age groups: n (%)				<0.001
<35	56 (1.5)	85 (1.9)	141 (1.7)	
35-39	105 (2.7)	104 (2.3)	209 (2.5)	
40-44	158 (4.1)	202 (4.6)	360 (4.4)	
45-49	270 (7.1)	255 (5.8)	525 (6.4)	
50-54	366 (9.6)	353 (8.0)	719 (8.7)	
55-59	487 (12.7)	609 (13.7)	1096 (13.3)	
60-64	580 (15.2)	571 (12.9)	1151 (13.9)	
65-69	514 (13.5)	567 (12.8)	1081 (13.1)	
70-74	496 (13.0)	696 (15.7)	1192 (14.4)	
75-79	383 (10.0)	400 (9.0)	783 (9.5)	
80-84	234 (6.1)	367 (8.3)	601 (7.3)	
85+	172 (4.5)	223 (5.0)	395 (4.8)	
DFD Characteristics				
Combined surface area (mm2): mean (sd)	450.9 (1277.6)	453.5 (1716.1)	452.2 (1512.7)	0.966
Acute Charcot: n(%)				0.605
No	1825 (83.2)	2467 (84.1)	4292 (83.7)	
Yes	89 (4.1)	106 (3.6)	195 (3.8)	
Risk classification: n(%)				< 0.001
Acute	1889 (86.1)	2636 (89.9)	4525 (88.3)	
At Risk	14 (0.6)	49 (1.7)	63 (1.2)	
High Risk	164 (7.5)	195 (6.7)	359 (7.0)	
Low Risk	13 (0.6)	52 (1.8)	65 (1.3)	

DFDS = diabetes-related foot disease service; DFD = diabetes-related foot disease; sd = standard deviation

Table 2. Unadjusted results

	Usual care (N=3821)	DFDS (N=4432)	Total (N=8253)	p-val.
Clinic visit within 2 days of referral: mean (sd)	0.53 (0.49)	0.52 (0.50)	0.53 (0.49)	0.421
Days from referral to visits: mean (sd)	6.1 (11.6)	5.5 (9.8)	5.8 (10.6)	0.067
Length of hospital stay: mean (sd)	8.9 (13.7)	7.5 (11.0)	8.2 (12.5)	0.003
Health State: n (%)				< 0.001
No DFD	221 (5.8)	323 (7.3)	544 (6.6)	0.006
DFD without infection	1358 (35.5)	1781 (40.2)	3139 (38.0)	< 0.001
DFD with infection	614 (16.1)	828 (18.7)	1442 (17.5)	0.002
Hospitalisation	1115 (29.2)	1042 (23.5)	2157 (26.1)	< 0.001
Minor Amputation	329 (8.6)	288 (6.5)	617 (7.5)	< 0.001
Major Amputation	38 (1.0)	31 (0.7)	69 (0.8)	0.142
Death	146 (3.8)	139 (3.1)	285 (3.5)	0.089

DFDS = diabetes-related foot disease service; sd = standard deviation; DFD = diabetes-related foot disease

The effects of the implementation of the DFDS initiative on selected outcomes were further examined by using generalised linear regressions. The finding confirmed that novel funding for DFDS was associated with positive changes. DFDS was associated with a reduction in inpatient LOS by 1 day (Appendix B). The duration of time from the referral to the first clinic visit reduced by 0.6 days with the introduction of the DFDS. In addition, the probability of being admitted and discharged within one day increased by 4%. The probability of attending a foot clinic service within two days of referral decreased by 1%, however this finding was not statistically significant. Health outcomes were not significantly or consistently associated with age, sex, or ethnicity.

3.2 PROGRESSION OF HEALTH STATES

The observed transitions between health states are presented in Figure 2. The predicted prevalence rate (i.e., proportions of non-absorbing health states), simulated using the estimated transition probability matrices, showed that for DFDS and usual care the majority of patients were estimated to transition to hospital over the five-year period, reflecting the observed data that the transition probabilities to hospitalisation were highest.

The novel funding DFDS, when compared to usual care, was associated with significant improvements in the number of patients and duration of time that they remained in state 1 (no DFD) or minor disease states (i.e., DFD with or without infection), and a significant reduction in the probability of being in more severe health states. Specifically, DFDS patients were less likely to transition to hospitalisation and major amputation compared to usual care patients. An exception is the probability of minor amputation, where the novel funded DFDS was associated with a significantly higher probability of being in this health state.

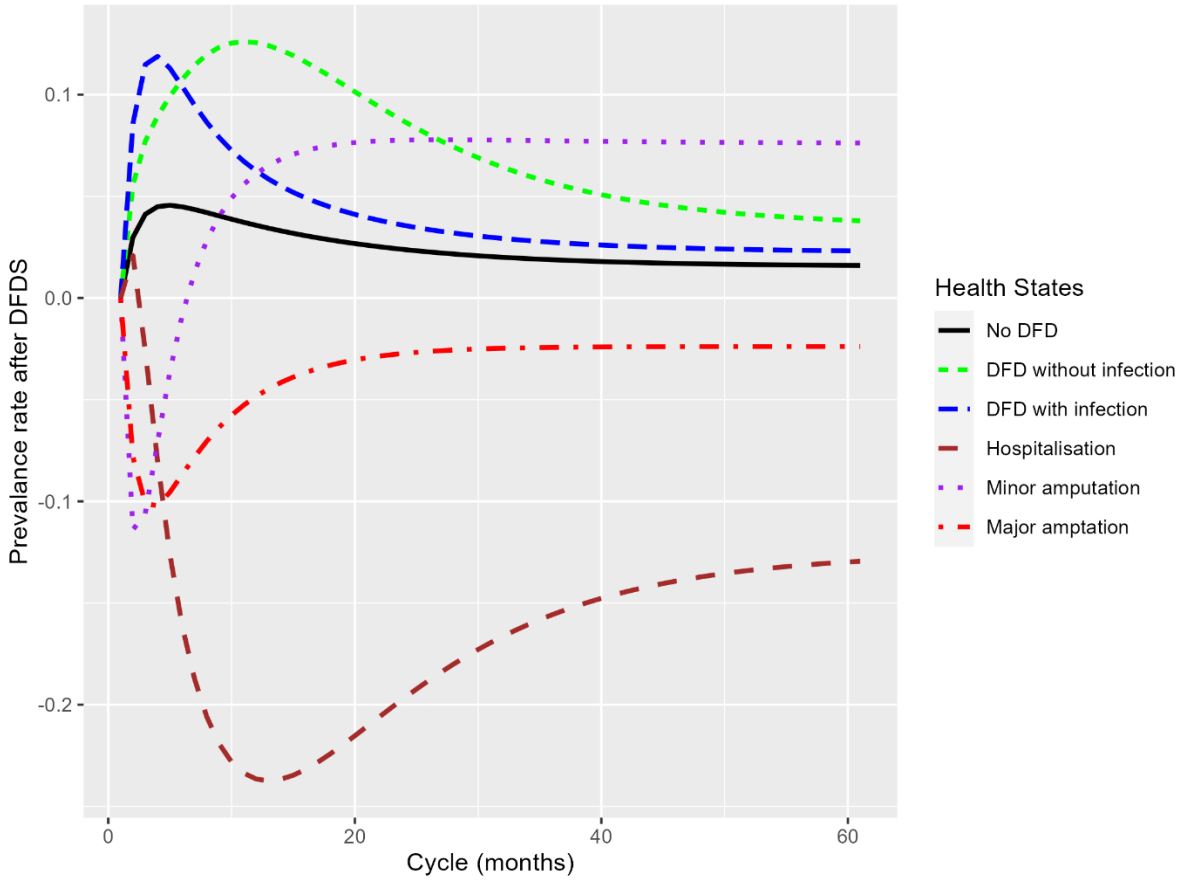

Figure 4. Changes in prevalence of Health States after DFDS

3.3 HEALTH-RELATED QUALITY OF LIFE & QUALITY ADJUSTED LIFE YEARS

Full account of the sub-study to estimate HRQoL weights are provided in Appendix A. In brief, estimates were derived from a total of 378 completed EQ-5D questionnaires from five HHSs across Queensland. Two participants were excluded from further analysis for single-item non-response. Participant characteristics and EQ-5D responses are presented in Appendix B Table 5 and Table 6.

Age-sex adjusted health-related quality of life utility estimates ranged from 0.452 for those with a current ulcer with infection to 0.573 for those previously healed (Table 3). The health-related quality utility index was statistically significantly lower among those with a current ulcer and infection compared to those previously healed; whereas there was no statistically significant difference for other health states.

Table 3. Predicted EQ-5D: Age-Sex adjusted utility index per Health State

Health State	Utility Value	Std. Err.	95% Confidence Interval	
Healed	0.5731	0.032	0.510	0.636
Current ulcer	0.5541	0.031	0.492	0.616
Current ulcer + infection	0.4521	0.047	0.359	0.545
Post new hospitalisation	0.5320	0.057	0.420	0.644
Minor amputation	0.5450	0.044	0.459	0.631
Major amputation	-0.1200	0.017	-0.152	-0.088

The average QALY of no DFD, DFD without infection, DFD with infection, hospitalisation, minor amputation, and major amputation included in the model were 0.57, 0.55, 0.45, 0.53, 0.54, -0.12, respectively. The death state was associated with zero QALY. Note that the QALY of major amputation was considered worse than death.

3.4 COSTS

The cost of usual care was adopted from Cheng et al.[20]. The cost of clinic care was estimated as the weighted average of the DFDS investment ($4,736,083) and the total clinic visits by health states since July 2019. The average costs of hospital admissions, minor and major amputation were estimated from the linked hospital admissions data. Costs were converted to 2021 price using the Australian consumer price index[30].

The unit costs for DFD without and with infections were $349.2 and $364.4 for the usual care model and $1,114.5 and $1,163.0 for the DFDS model. For both usual care and DFDS groups, the unit cost of costs associated with hospitalisation, minor amputation and major amputation were $11,410, $22,956.9 and $55,538.4, respectively. The first and last health state (i.e., no DFD and death) incur zero costs. Cost simulations were conducted using a uniform distribution with 10% variation from the unit costs. The aggregated costs were estimated as the sum products of unit costs and the number of visits within each health state. The present-value costs, discounted at the rate of 5%/year, over 60 cycles for usual care was $10,588.2 [95% confidence interval: $10,558.7; $10,617.8] while the respective figure for DFDS was $2,159.2 [$2,146.8; $2,171.5].

3.5 ECONOMIC ANALYSIS

3.5.1 INCREMENTAL COST-EFFECTIVENESS RATIO (ICER)

The incremental cost change was -$8,422 [-$8,461 - $8,385] and incremental QALY change was 0.05 [0.04,0.06]. Thus, the DFDS model was cost-saving, dominating the usual care model (Figure 3).

To examine the robustness of the cost-effectiveness findings against the uncertainty that affects costs and QALY, a probabilistic sensitivity analysis was conducted using 1500 iterations to examine the sensitivity of the cost-effectiveness findings against the uncertainty in the model input parameters. We find that the economic results are robust with all iterations resulting in a cost-saving. Overall, the probabilistic sensitivity analysis showed that the DFDS has a 93.53% likelihood of being cost-effective.

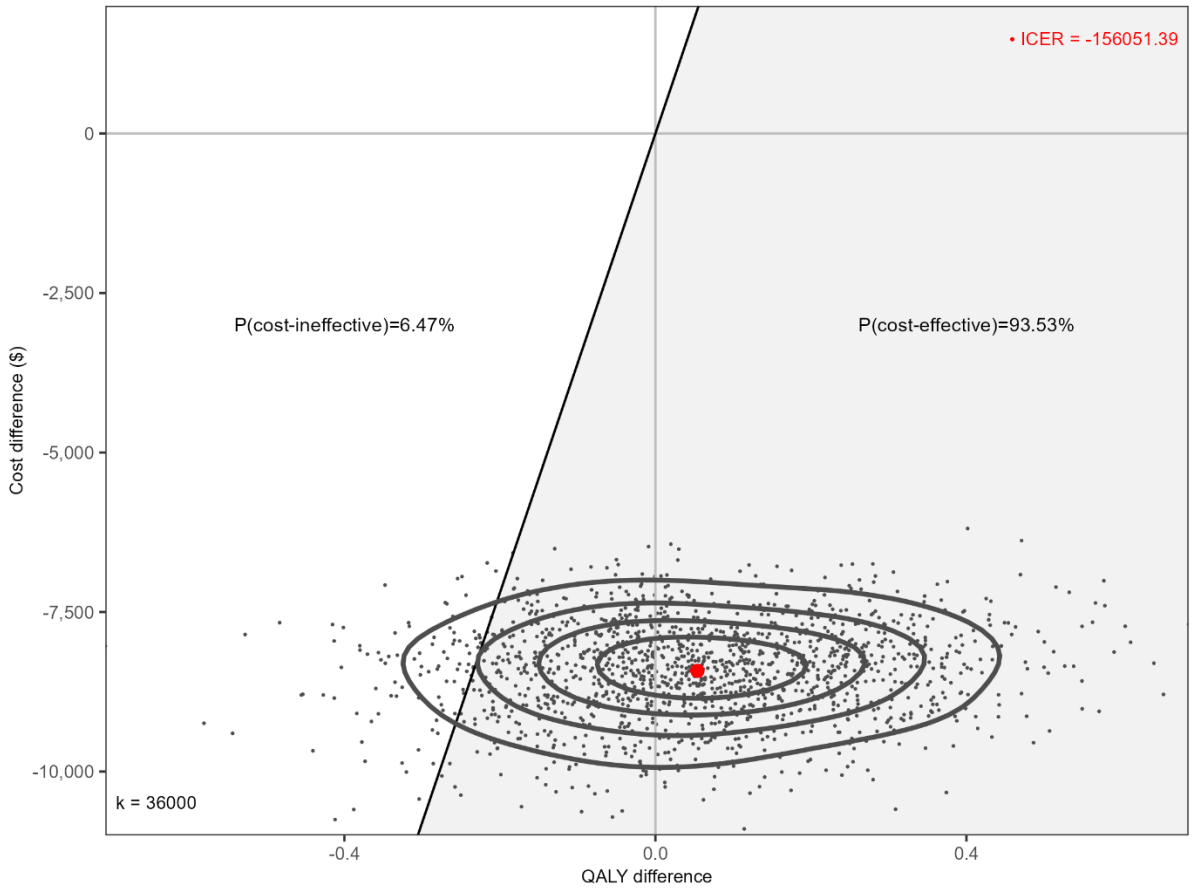

Figure 5. Probabilistic Sensitivity Analysis

3.5.2 RETURN ON INVESTMENT (ROI)

Owing to the highly cost-effective outcome, the DFDS also produced a high ROI, including the value of improving QALY at the WTP of $36,000 as benefits. On average, one dollar invested in the DFDS generated a return of $7.72 [$7.49, $7.95]. Even if the value of QALY gain was excluded, the estimated return on investment is still substantial at $6.46 [$6.43, $6.47]

4 DISCUSSION

DFD is now the leading cause of hospitalisation, disability, and amputation burdens in Queensland and globally [1-7]. Research has demonstrated that DFD burdens can be significantly reduced with improved access to, and quality of, multi-disciplinary ambulatory DFD care. As a result of the increased DFD burden, the Queensland Department of Health initiated a new funding model designed to incentivise improved DFD service models based on current research and national and international guidelines. This evaluation examined the cost-effectiveness of the novel funding model (DFDS) for people with DFD across Queensland compared to the current activity-based funding model. To achieve this aim, a secondary linked data set of hospital admissions and death registry records for patients who have attended a foot clinic service in Queensland was established.

Findings from descriptive and regression analyses revealed that the DFDS was associated with better health outcomes (e.g., lower LOS and shorter duration from referral to the first foot clinic visit). Applying a multi-state survival and Bayesian Markov model to examine the cost-effectiveness of the DFDS, we found that the DFDS was cost-saving compared to the usual care model. The main reasons for the savings in costs are because of a lowered probability of hospitalisation as well as minor and major amputations, which have a substantially higher unit cost compared to that of general clinical foot services.

Our findings are in line with a previous study conducted by Cheng et al. [20], who also found that a similar model for diabetes-related foot services was cost-saving. The magnitude of our cost-saving figure ($8,430) was also similar, all be it marginally less than that of Cheng et al. ($9,000-$12,000). Specifically, the value of our incremental QALY change was smaller (0.06) compared to that of Cheng et al. (0.13-0.16), but our estimate was significant, while Cheng et al. did not find the optimal care service to be significantly associated with a QALY improvement.

The main limitation of this study is the study design. For this evaluation it was not feasible to assign individuals randomly to control and DFDS groups. Thus, the effects of the DFDS on outcomes may be biased by factors that also occurred in the same study period (e.g., technological improvements or unrelated policy changes). Additionally, the absence of linked emergency department admissions data as well as Medicare Benefits Schemes and Pharmaceutical Benefits Schedule data has not allowed for a full estimate of costs and benefits from an Australian publicly funded health service perspective. As a result of the unavailability of these data, including hospital cost data for the period after 30th June 2019, an assumption that the unit cost of hospitalisations remained unchanged during the DFDS period was applied. This assumption is unlikely to affect the findings because healthcare costs, especially in the public sector, are highly regulated and adjusted for only periodically. Also, whilst preferably we would assess the results of the introduction of the state-wide initiative for each HHS separately, we were not able to due to data constraints (i.e., not enough observational data). As each HHS retained autonomy as to specific programs to meet the KPI targets associated with the new model it is likely that there could be significant heterogeneity in the results. In time and with a greater pool of available observations for analysis, this could be explored further.

5 CONCLUSION

We find robust evidence that the new DFDS model to be cost-effective compared to usual care. The main driver for the cost savings was the lowered probability of hospitalisation as

well as minor and major amputations, which all have a substantially higher unit cost compared to that of general clinical foot service provision. On average, one dollar invested in the new funding model is associated with a return of $8.40 with a 98.33% likelihood of being cost-effective. Given the substantial increase in the economic burden of DFD globally and the resultant strain on finite healthcare resources, our findings demonstrate the importance of this new funding model for DFD services be considered for wider implementation by governments and healthcare providers.

6 REFERENCES

1. Armstrong DG, Boulton AJ, Bus SA. Diabetic foot ulcers and their recurrence. New England Journal of Medicine. 2017;376(24):2367-75.
2. Lazzarini PA. The burden of foot disease in inpatient populations: Queensland University of Technology; 2016.
3. Lazzarini PA, Gurr JM, Rogers JR, Schox A, Bergin SM. Diabetes foot disease: the Cinderella of Australian diabetes management? Journal of foot and ankle research. 2012;5(1):24.
4. Lazzarini PA, Hurn SE, Kuys SS, Kamp MC, Ng V, Thomas C, et al. The silent overall burden of foot disease in a representative hospitalised population. International wound journal. 2017;14(4):716-28.
5. Lazzarini PA, Pacella RE, Armstrong DG, Van Netten JJ. Diabetes-related lower-extremity complications are a leading cause of the global burden of disability. Diabetic Medicine. 2018;35(9):1297-9.
6. Lazzarini PA, van Netten JJ, Fitridge RA, Griffiths I, Kinnear EM, Malone M, et al. Pathway to ending avoidable diabetes-related amputations in Australia. Medical Journal of Australia. 2018;209(7):288-90.
7. van Netten JJ, Lazzarini PA, Fitridge R, Kinnear EM, Griffiths I, Malone M, et al. Australian diabetes-related foot disease strategy 2018-2022: the first step towards ending avoidable amputations within a generation 2017 [cited 2021 22/07/2021]. Available from: https://diabeticfootaustralia.org/wp-content/uploads/National-Strategy-to-end-avoidable-amputations-in-a-generation-final-1.pdf.
8. Schaper NC, van Netten JJ, Apelqvist J, Bus SA, Hinchliffe RJ, Lipsky BA, et al. Practical Guidelines on the prevention and management of diabetic foot disease (IWGDF 2019 update). Diabetes/Metabolism Research and Reviews. 2020;36:e3266.
9. Nickinson AT, Bridgwood B, Houghton JS, Nduwayo S, Pepper C, Payne T, et al. A systematic review investigating the identification, causes, and outcomes of delays in the management of chronic limb-threatening ischemia and diabetic foot ulceration. Journal of vascular surgery. 2019.
10. Lazzarini PA, O'Rourke SR, Russell AW, Derhy PH, Kamp MC. Reduced incidence of foot-related hospitalisation and amputation amongst persons with diabetes in Queensland, Australia. PLoS One. 2015;10(6).
11. Lazzarini PA, Fitridge R. Regional variations in amputation rates: are regional diabetic foot services the reason? ANZ journal of surgery. 2019;89(7-8):796-7.
12. Digital N. National Diabetes Foot Care Audit, 2014-2018. In: Digital N, editor. England: NHS; 2019.
13. Albright RH, Manohar NB, Murillo JF, Kengne LAM, Delgado-Hurtado JJ, Diamond ML, et al. Effectiveness of Multidisciplinary Care Teams in Reducing Major Amputation Rate in Adults with Diabetes: A Systematic Review & Meta-Analysis. Diabetes Research and Clinical Practice. 2020:107996.
14. Monteiro-Soares M, Russell D, Boyko E, Jeffcoate W, Mills J, Morbach S. IWGDF Guideline on the classification of diabetic foot ulcers. Diabetes Metab Res Rev. 2019.
15. Bus SA, Lavery L, Monteiro-Soares M, Rasmussen A, Raspovic A, Sacco I. IWGDF guideline on the prevention of foot ulcers in persons with diabetes. Diabetes Metab Res Rev. 2019.
16. Bus SA, Armstrong DG, Gooday C, Jarl G, Caravaggi C, Viswanathan V, et al. IWGDF guideline on offloading foot ulcers in persons with diabetes. 2019.

17. Bus S, Van Netten J, Hinchliffe R, Apelqvist J, Lipsky B, Schaper N, et al. Standards for the development and methodology of the 2019 International Working Group on the Diabetic Foot guidelines. Diabetes/Metabolism Research and Reviews. 2020:e3267.
18. (NICE) NIfCE. Diabetic foot problems: prevention and management NICE guideline [NG19]. London, UK: NICE; 2019.
19. (ADS) NAoDCNaADS. NADC Collaborative Interdisciplinary Diabetes High Risk Foot Services Standards Version 1.1 Sydney, Australia: National Association of Diabets Centres; 2018.
20. Cheng Q, Lazzarini PA, Gibb M, Derhy PH, Kinnear EM, Burn E, et al. A cost-effectiveness analysis of optimal care for diabetic foot ulcers in Australia. International wound journal. 2017;14(4):616-28.
21. Zhang Y, van Netten JJ, Baba M, Cheng Q, Pacella R, McPhail SM, et al. Diabetes-related foot disease in Australia: a systematic review of the prevalence and incidence of risk factors, disease and amputation in Australian populations. J Foot Ankle Res. 2021;14(1):8.
22. van Netten JJ, Bus SA, Apelqvist J, Lipsky BA, Hinchliffe RJ, Game F, et al. Definitions and criteria for diabetic foot disease. Diabetes/Metabolism Research and Reviews. 2019:e3268.
23. Lazzarini PA, Hurn SE, Kuys SS, Kamp MC, Ng V, Thomas C, et al. Foot Complications in a Representative Australian Inpatient Population. J Diabetes Res. 2017;2017:4138095.
24. Ortegon MM, Redekop WK, Niessen LW. Cost-effectiveness of prevention and treatment of the diabetic foot: a Markov analysis. Diabetes care. 2004;27(4):901-7.
25. Tennvall GR, Apelqvist J. Prevention of diabetes-related foot ulcers and amputations: a cost-utility analysis based on Markov model simulations. Diabetologia. 2001;44(11):2077-87.
26. Branch QHS. Queensland Hospital Admitted Patient Data Collection (QHAPDC): Manual of instructions and procedures for reporting of QHAPDC data. Brisbane, Australia: Department of Health; 2013 [Available from: http://www.health.qld.gov.au/hsu/default.asp
27. Baio G. Bayesian methods in health economics: CRC Press Boca Raton; 2013.
28. Jahn B, Kurzthaler C, Chhatwal J, Elbasha EH, Conrads-Frank A, Rochau U, et al. Alternative conversion methods for transition probabilities in state-transition models: validity and impact on comparative effectiveness and cost-effectiveness. Medical Decision Making. 2019;39(5):509-22.
29. Edney LC, Afzali HHA, Cheng TC, Karnon J. Estimating the reference incremental cost-effectiveness ratio for the Australian health system. PharmacoEconomics. 2018;36(2):239-52.
30. Australian Bureau of Statistics. Consumer Price Index, Australia. In: Statistics ABo, editor. Canberra2022.
31. Health TAGDo. The Pharmaceutical Benefits Advisory Committee (PBAC) guidelines (version 5.0). Canberra, Australia; 2016.
32. Cohen J. Statistical power analysis for the behavioral sciences: Academic press; 2013.
33. Redekop W, Stolk E, Kok E, Lovas K, Kalo Z, Busschbach J. Diabetic foot ulcers and amputations: estimates of health utility for use in cost-effectiveness analyses of new treatments. Diabetes & metabolism. 2004;30(6):549-56.
34. Viney R, Norman R, King MT, Cronin P, Street DJ, Knox S, et al. Time trade-off derived EQ-5D weights for Australia. Value in Health. 2011;14(6):928-36.
35. Tennvall GR, Apelqvist J. Health-related quality of life in patients with diabetes mellitus and foot ulcers. Journal of Diabetes and its Complications. 2000;14(5):235-41.

36. Wukich DK, Raspovic KM. Assessing Health-Related Quality of Life in Patients With Diabetic Foot Disease: Why Is It Important and How Can We Improve? The 2017 Roger E. Pecoraro Award Lecture. Diabetes Care. 2018;41(3):391-7.
37. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of life research. 2011;20(10):1727-36.
38. Norman R, Cronin P, Viney R. A pilot discrete choice experiment to explore preferences for EQ-5D-5L health states. Applied health economics and health policy. 2013;11(3):287-98.

APPENDIX A. CLINICAL DIAGNOSIS CODES USED FOR HEALTH STATE IDENTIFICATION

Table 4. Criteria by which episodes of care are identified based in clinical diagnosis coding

Criteria	ICD	Description	Other diagnosis codes required / Comments
1. Minor Amputation	[1533] 44338-00 [1533] 44358-00 [1533] 44361-00 [1533] 44361-01 [1533] 44364-00 [1533] 44364-01 [1533] 90557-00	Amputation of toe Amputation of toe including metatarsal bone Disarticulation through ankle Amputation of ankle through malleoli of tibia and fibula Mid-tarsal amputation Trans-metatarsal amputation Disarticulation through toe	At least one of: E10-E14
2. Major amputation	[1505] 44367-01 [1505] 44367-02 [1484] 44367-00 [1484] 44370-00 [1484] 44373-00	Disarticulation at knee Amputation below knee Amputation above knee Amputation at hip Hindquarter amputation	At least one of: E10-E14
3. Debridement of foot/ankle wound	9066500 9068601 3002300 3002301 9066500 9066500 9068601 3002300 3002301 9066500	Excisional debridement of skin and subcutaneous tissue Nonexcisional debridement of skin and subcutaneous tissue (includes vacuum dressing) Excisional debridement of soft tissue Excisional debridement of soft tissue involving bone or cartilage Excisional debridement of skin and subcutaneous tissue Excisional debridement of skin and subcutaneous tissue Nonexcisional debridement of skin and subcutaneous tissue (includes vacuum dressing) Excisional debridement of soft tissue Excisional debridement of soft tissue involving bone or cartilage Excisional debridement of skin and subcutaneous tissue	At least one of: E10-E14 AND At least one of: L89, I70.23, L02.43, L97.0, L03.02, L03.13, L03.14. This ensures the EOC was foot/leg

APPENDIX B. QUALITY OF LIFE STUDY INCLUDING QUESTIONNAIRE

Procedures and Recruitment

Patients were recruited among those attending one of 18 outpatient high-risk foot clinics in the period from November 2020 to April 2021 across 5 hospital and health service areas in Queensland, Australia. During a patient-scheduled consultation, either the treating clinician or clinic administrative staff, recruited patients to take part in the study. Patients were included in the study if they were: aged 18 and over; had a current or healed DFD including major or minor amputation; a citizen or permanent resident of Australia or New Zealand; and had the demonstrative cognitive ability and willingness to cooperate with the study procedures. Patients were excluded if they demonstrated inadequate written and spoken English or had previously taken part in the survey. All surveys were completed using paper-based approaches completed at the time of study enrolment and provided to the treating clinician. The treating clinician was then responsible for providing information on the patient demographics, current health state and previous history.

Sample size calculation

A minimum sample size of 280 completed surveys was considered necessary based on a power of 0.8, a significant level (alpha) of 0.05, and a modest R^2 of 0.05. The R^2 was estimated using Cohen's f2 effect size [32]: $f2=R^2/(1-R^2)$ and an effect size (minimal difference between DFD health states of 0.05) based on previous estimates from the literature [33] and previously considered a minimally clinically important difference in the EQ-5D utility index [34]. Quota sampling was used to ensure sufficient observations across the *a priori* defined DFD health states. However, due to the low expected incidence of amputations, a single quota was used for both the minor and major amputation health states. Based on a total sample size of 280, a quota sample of 56 for each of the five health states (after collapsing major and minor amputation health states) was adopted. When a health state reached the target quota sampling for that health state, recruitment for patients for that health state ceased.

Questionnaire

The EQ-5D:5L is a generic, standardised instrument that is widely used to measure health related quality of life and isdesigned for self-completion and postal surveys. It has been widely used and tested for validity, reliability, and generality [35] for use in different diseases and health conditions [36, 37], as well as in the general populations of several countries [37]. The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each of the dimensions have five response options: no problems, slight problems, moderate problems, severe problems, and extreme problems. Patients are asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. The patient's response is expressed as a 1-digit number for that dimension. The individual digits for each of the five dimensions are then combined into a 5-digit number that describes the patient's health state as per the EQ-5D descriptive system. The Australian valuation set [38], which is a set of weights for each of the levels in the five EQ-5D dimensions, is then used to convert participants' EQ-5D health state into a health related quality of life utility index value. The questionnaire EQ-5D also contains a visual analogue scale (VAS) where patients are asked to indicate how they rate their present health on a thermometer-like scale that ranges from 0 to 100, where the "worst imaginable health state" represents 0 and the "best imaginable health state" represents 100.

Statistical analyses

The health-related quality of life utility index for each health state will be estimated using a multi-variate regression analysis. Main covariates used in the regression for health-related quality of life index include the DFD health state, age, and sex of patients. The predicted health-related quality of life for each DFD health state will be estimated using a second-stage statistical test.

Findings

A total of 378 questionnaires were returned with single-item non-response for two patients (which were excluded from further analysis). The mean age of respondants was 63.1 years (Std. Dev. 12.2), with the majority being male (75.4%) (Table 5). Of the sample, 42.3% had a previous amputation, and 61.6% had been previously hospitalised for DFD. Three of the five quota samples were met (healed, current ulcer without infection, current amputation) with 51/56 (91.1%) and 36/56 (64.3%) of the quotas met for current ulcer with an infection and post new hospitalisation, respectively. Of those included in the combined amputation health state, 58 of60 (96.7%) were minor amputations.

Table 5. EQ-5D Questionnaire Participant Characteristics

Characteristics	**N = 378**
Age (mean, sd)	63.1 (12.2%)
Sex (n, %)	
Male	285 (75.4%)
Female	93 (24.6%)
Hospital Health Service (n, %)	
1	40 (10.6%)
2	52 (13.8%)
3	103 (27.2%)
4	129 (34.1%)
5	54 (14.3%)
Clinical history	
Previous amputation	160 (42.3%)
Previous DFD hospitalisation	233 (61.6%)
Health state (n, %)	
Prev heal w/o current DFD	115 (29.9%)
Current DFD w/o Infection	116 (30.2%)
Current DFD with Infection	51 (13.3%)
Post new hospitalisation	36 (9.4%)
avg time since, weeks	1.5
Post New minor amputation	58 (15.1%)
avg time since, weeks	5.1
Post new major amputation	2 (0.5%)
avg time since, weeks	7.5
Current infection[2]	76 (20.2%)

Sd = standard deviation; DFD = diabetes-related foot disease

Apart from those with a current DFD and infection, the majority of respondants answered either "no problems" or "slight problems" to all the EQ-5D questions (Table 6). For respondants with a current DFD and infection, the majority of responses indicated moderate or greater severity in the domains of 'mobility' and 'usual activities'. The impact on health-related quality of life was lowest with respect to self-care (disutility estimates ranged from 0.03 to 0.05) and, although relatively equal among the other domains, was health-related quality of life was slightly higher for usual activities (range: 0.10, 0.14 across health states) and Anxiety and depression (range: 0.11, 0.15 across health states).

Table 6. EQ-5DL Participant Responses

Domain, Response	Prev heal w/o current	Current DFD w/o Inf	Current DFD + Inf	Post new hosp	Post New amp
	n (%)	n (%)	n (%)	n (%)	n (%)
Mobility					
1	35 (30.4%)	21 (18.1%)	10 (19.6%)	9 (25%)	19 (32.8%)
2	29 (25.2%)	42 (36.2%)	11 (21.6%)	11 (30.6%)	10 (17.2%)
3	32 (27.8%)	31 (26.7%)	18 (35.3%)	9 (25%)	20 (34.5%)
4	15 (13%)	16 (13.8%)	9 (17.6%)	4 (11.1%)	5 (8.6%)
5	4 (3.5%)	6 (5.2%)	3 (5.9%)	3 (8.3%)	4 (6.9%)
Disutility (mean, sd)	-0.09 (0.09)	-0.10 (0.09)	-0.11 (0.1)	-0.10 (0.1)	-0.09 (0.09)
Self-care					
1	76 (66.1%)	78 (67.2%)	31 (60.8%)	21 (58.3%)	37 (63.8%)
2	19 (16.5%)	24 (20.7%)	9 (17.6%)	8 (22.2%)	11 (19%)
3	18 (15.7%)	11 (9.5%)	5 (9.8%)	4 (11.1%)	8 (13.8%)
4	1 (0.9%)	0 (0%)	4 (7.8%)	3 (8.3%)	1 (1.7%)
5	0 (0%)	3 (2.6%)	2 (3.9%)	0 (0%)	1 (1.7%)
Disutility (mean, sd)	-0.03 (0.04)	-0.03 (0.06)	-0.05 (0.08)	-0.04 (0.06)	-0.03 (0.06)
Usual activities					
1	36 (31.3%)	37 (31.9%)	11 (21.6%)	9 (25%)	16 (27.6%)
2	35 (30.4%)	36 (31%)	13 (25.5%)	8 (22.2%)	12 (20.7%)
3	31 (27%)	27 (23.3%)	13 (25.5%)	11 (30.6%)	19 (32.8%)
4	9 (7.8%)	8 (6.9%)	10 (19.6%)	5 (13.9%)	4 (6.9%)
5	3 (2.6%)	8 (6.9%)	4 (7.8%)	3 (8.3%)	7 (12.1%)
Disutility (mean, sd)	-0.10 (0.08)	-0.10 (0.09)	-0.14 (0.1)	-0.13 (0.1)	-0.12 (0.1)
Pain/discomfort					
1	33 (28.7%)	37 (31.9%)	14 (27.5%)	12 (33.3%)	19 (32.8%)
2	31 (27%)	27 (23.3%)	14 (27.5%)	12 (33.3%)	16 (27.6%)
3	36 (31.3%)	35 (30.2%)	14 (27.5%)	6 (16.7%)	18 (31%)
4	12 (10.4%)	11 (9.5%)	6 (11.8%)	6 (16.7%)	3 (5.2%)
5	3 (2.6%)	6 (5.2%)	3 (5.9%)	0 (0%)	2 (3.4%)
Disutility (mean, sd)	-0.08 (0.08)	-0.09 (0.09)	-0.10 (0.1)	-0.08 (0.09)	-0.07 (0.08)
Anxiety/Depression					
1	52 (45.2%)	54 (46.6%)	16 (31.4%)	17 (47.2%)	26 (44.8%)
2	34 (29.6%)	35 (30.2%)	17 (33.3%)	11 (30.6%)	19 (32.8%)
3	19 (16.5%)	18 (15.5%)	14 (27.5%)	3 (8.3%)	11 (19%)
4	6 (5.2%)	4 (3.4%)	3 (5.9%)	3 (8.3%)	2 (3.4%)
5	2 (1.7%)	5 (4.3%)	1 (2%)	2 (5.6%)	0 (0%)
Disutility (mean, sd)	-0.11 (0.12)	-0.11 (0.12)	-0.15 (0.12)	-0.12 (0.14)	-0.11 (0.11)
EQ-5D index	0.58 (0.31)	0.55 (0.34)	0.45 (0.40)	0.52 (0.37)	0.55 (0.32)

DFD = diabetes-related foot disease; sd = standard deviation

Economic Evaluation of a Novel Funding Model for Diabetic Foot Disease

Participant Questionnaire

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1) **What is the study about?** You are invited to take part in this research project, *Economic Evaluation of the Queensland Health High-Risk Foot Service Strategy*. This is because you have recently received care for your wound on your foot from a Queensland Health High Risk Foot Clinic. The research project is aiming to examine the impact of foot wounds on health-related quality of life. Information from this study will help us evaluate the quality of life and potential cost-effectiveness of new and existing services to improve the health outcomes for persons with diabetic foot disease.

2) **Who is carrying out the study?** This research project has been initiated by a group of researchers from Griffith University, Queensland University of Technology and Queensland Health. The project is led by Associate Professor Josh Byrnes, Griffith University and is funded by Queensland Health. It is part of a larger study that is assessing the cost-effectiveness of the introduction of a new funding model for people with diabetes-related foot disease.

3) **What does the study involve?** To participate in this research project, you will be expected to complete a short paper-based survey provided by a member of the research team during your visit to the High Risk Foot Clinic. The survey will ask you questions about your health-related quality of life and will take approximately 3-5 minutes to complete. Once completed, you will be asked to return it to your treating clinician who will then complete the information at the end of this survey related to your foot ulceration. All information that you and your treating clinician provide will remain anonymous and confidential.

4) **What are the possible benefits and risks to you of participating?** It is not expected that you will receive any direct benefits from this research. However, findings of this research project will help to inform health policy makers about the impact on patients' health related quality of life with diabetes-related foot disease which may lead to improvements in patient care in the future. It is not expected that participating in this research project should cause any discomfort, risk of harm or side effects to what you would expect from usual care at a High-Risk Foot Clinic.

5) **Will I incur any costs by participating in the study?** You will not incur any costs by participating in this research.

6) **Will I receive the results of the study?** A summary of the findings of the evaluation will be made available to participants upon request.

7) **Confidentiality and disclosure of information.** The information collected from all participants will be anonymous. We will use combined summary results, when we present information to ensure that any reports arising from the study will not identify participants. Furthermore, all information collected during this study will not be disclosed to third parties, except if there were a need to meet government, legal or other regulatory authority requirements. All data from this study will be retained on a password protected electronic file at Griffith University for a period of five years before being destroyed. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Any publications and presentations would include de-identified data only and in no way identify individuals.

8) **Can I withdraw from the study?** Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with your healthcare provider/s.

9) **How can I obtain further information?** If you would like further information concerning this project you can contact the study coordinator Josh Byrnes, (07) 3735 9107, j.byrnes@griffith.edu.au.

10) **What can I do if I have a complaint or a concern?** If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact: Anne Carle, The Prince Charles Hospital, Metro North Health and Hospital Service: ph 07 3139 4198/ 07 3139 4500, email ResearchTPCH@health.qld.gov.au.

Completion of this survey will be taken as your consent to participate in the research.

Patient to Complete

Today's date (dd/mm/yyyy): _____

HEALTH-RELATED QUALITY OF LIFE

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about	☐
I have slight problems in walking about	☐
I have moderate problems in walking about	☐
I have severe problems in walking about	☐
I am unable to walk about	☐

SELF-CARE

I have no problems washing or dressing myself	☐
I have slight problems washing or dressing myself	☐
I have moderate problems washing or dressing myself	☐
I have severe problems washing or dressing myself	☐
I am unable to wash or dress myself	☐

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities	☐
I have slight problems doing my usual activities	☐
I have moderate problems doing my usual activities	☐
I have severe problems doing my usual activities	☐
I am unable to do my usual activities	☐

PAIN / DISCOMFORT ☐

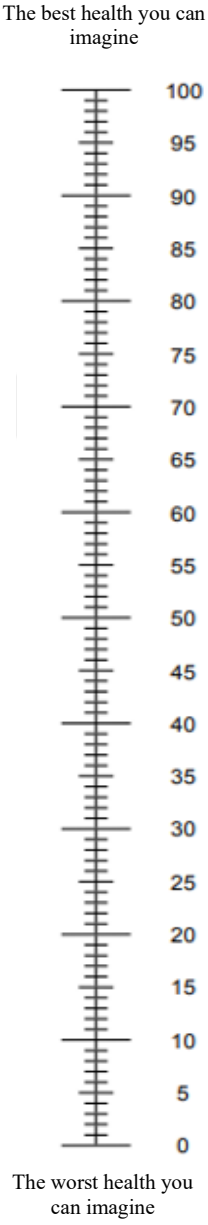
I have no pain or discomfort	☐
I have slight pain or discomfort	☐
I have moderate pain or discomfort	☐
I have severe pain or discomfort	☐
I have extreme pain or discomfort	☐

ANXIETY / DEPRESSION

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE. PLEASE RETURN TO YOUR TREATING CLINICIAN.

For Clinician Use Only

Facility:_____

Demographic Information

Age (in years)

☐ _____

Gender

☐ Male ☐ Female

Medical and foot history

☐ Previously healed foot ulcer	☐ Previous amputation	☐ Previous foot hospitalisation
☐ Current foot ulcer	☐ Current amputation	☐ New foot hospitalisation

Amputation

☐ Minor (below ankle) ☐ Major (above ankle)

Infection

☐ Yes ☐ No ☐ N/A

☐ Mild foot infection

☐ Moderate foot infection

Thank you for completing this form. Please scan and email to j.byrnes@griffith.edu.au.

APPENDIX C. EFFECTS OF DFDS ON SELECTED OUTCOMES

Table 7. Effects of DFDS on selected outcomes (generalised linear regressions)

Selected outcomes	Same-day admission		Inpatient LOS		Two-day visits		Referral duration	
	Coef.	p-val.	Coef.	p-val.	Coef.	p-val.	Coef.	p-val.
Intercept	0.25	<0.01	10.64	<0.01	0.50	<0.01	6.65	<0.01
DFDS	0.04	<0.01	-1.06	0.03	-0.01	0.46	-0.57	0.06
Sex (Male=1)	-0.06	<0.01	-0.73	0.18	0.01	0.44	-0.03	0.92
Ethnicity (Indigenous =1)	0.15	<0.01	1.07	0.10	0.16	<0.01	-0.70	0.11
Age (ref<35 years)								
35-39	-0.17	0.09	-0.72	0.81	0.09	0.15	-2.06	0.13
40-44	0.18	0.06	-4.11	0.13	0.09	0.12	-2.11	0.09
45-49	0.05	0.59	-2.14	0.43	-0.01	0.90	0.20	0.86
50-54	-0.09	0.35	-0.36	0.89	0.00	0.95	-0.42	0.70
55-59	0.00	0.96	-2.04	0.44	0.02	0.71	-0.74	0.49
60-64	-0.12	0.20	0.30	0.91	0.01	0.89	-0.63	0.55
65-69	0.02	0.85	-1.79	0.50	0.01	0.87	0.16	0.88
70-74	0.06	0.48	-1.58	0.55	-0.03	0.61	-0.16	0.88
75-79	0.08	0.38	-1.56	0.56	0.00	0.98	-0.29	0.79
80-84	0.16	0.08	-3.59	0.18	-0.04	0.50	-0.24	0.83
85+	-0.01	0.96	-0.06	0.98	0.04	0.48	-0.89	0.46

DFDS = diabetes-related foot disease; LOS = length of stay; Coef. = coefficient

APPENDIX D. OBSERVED TRANSITIONS BETWEEN HEALTH STATES

The observed transitions between health states were somewhat surprising, finding that the mortality risk was highest among people with no DFD (Table 8). The sole exception is the mortality risk of patient with a major amputation in the DFDS group. Also, probabilities of being admitted to the hospital were highest among all health states, suggesting that most patients visiting the clinic would have a severe foot issue. Sub-study 3 found that patients could transition between different health states, including reversing poor health states, with the exception of major amputations who tended to remain in that health state until death.

The observed transitions in Table 7-1 were based on 14 months of data for the usual care model (1 May 2018 to 30 June 2019) and 18 months of data for the DFDS model with novel funding (30 June 2019 to 31 December 2020). Based on the literature, cost-effectiveness was calculated in a monthly cycle with a time horizon of five years (i.e., 60 cycles); the transition probabilities were converted to monthly figures using the Eigen decomposition approach [28], which the literature has shown a reduced bias compare to the commonly used method of element-wise exponentiation[20]. The converted transition probabilities matrices were then used as priors for the Bayesian estimation. Results of the Bayesian estimates (Table 9) show that at the monthly cycle, the probability of remaining in the same health state was highest among all states. Also, the scale reduction parameter ($\hat{R}$) were all less than the rule-of-thumb value of 1.1, suggesting that the Bayesian model was converged and hence estimated parameters are the best candidates achievable from the model.

Table 8. Observed Transitions Between Health States

	To states: n(%)						
From states	1	2	3	4	5	6	7
Usual care							
1	16 (28.57)	12 (21.43)	5 (8.93)	15 (26.79)	0 (0)	1 (1.79)	7 (12.5)
2	14 (2.12)	153 (23.15)	31 (4.69)	276 (41.75)	96 (14.52)	7 (1.06)	84 (12.71)
3	10 (2.83)	45 (12.75)	21 (5.95)	179 (50.71)	73 (20.68)	9 (2.55)	16 (4.53)
4	6 (0.72)	71 (8.52)	54 (6.48)	530 (63.63)	124 (14.89)	19 (2.28)	29 (3.48)
5	3 (1.57)	35 (18.32)	17 (8.9)	90 (47.12)	36 (18.85)	2 (1.05)	8 (4.19)
6	0 (0)	1 (3.57)	0 (0)	25 (89.29)	0 (0)	0 (0)	2 (7.14)
DFDS							
1	7 (16.28)	9 (20.93)	2 (4.65)	14 (32.56)	3 (6.98)	0 (0)	8 (18.6)
2	23 (3.84)	134 (22.37)	37 (6.18)	259 (43.24)	63 (10.52)	7 (1.17)	76 (12.69)
3	3 (0.84)	44 (12.36)	31 (8.71)	158 (44.38)	91 (25.56)	7 (1.97)	22 (6.18)
4	0 (0)	42 (5.68)	22 (2.98)	538 (72.8)	102 (13.8)	15 (2.03)	20 (2.71)
5	4 (2.8)	31 (21.68)	11 (7.69)	59 (41.26)	29 (20.28)	2 (1.4)	7 (4.9)
6	0 (0)	0 (0)	0 (0)	14 (70.0)	0 (0)	0 (0)	6 (30)

Notes: health states are 1=No DFD, 2=DFD no infection, 3=DFD with infection, 4=Hospitalisation, 5=Minor Amputation, 6=Major amputation, 7=Dead

Table 9. Estimated Transition Probabilities

	Usual care			DFDS		
	Mean	SD	$\hat{R}$	Mean	SD	$\hat{R}$
P[1,1]	0.585	0.061	1.006	0.798	0.056	1.002
P[2,1]	0.004	0.003	1.003	0.013	0.005	1.004
P[3,1]	0.003	0.003	1.003	0.003	0.003	1.003
P[4,1]	0.001	0.001	1.004	0.001	0.001	1.004
P[5,1]	0.010	0.007	1.001	0.007	0.007	1.001
P[6,1]	0.030	0.028	1.006	0.036	0.035	1.002
P[1,2]	0.112	0.038	1.001	0.062	0.034	1.001
P[2,2]	0.797	0.016	1.004	0.897	0.013	1.001
P[3,2]	0.003	0.003	1.003	0.003	0.003	1.003
P[4,2]	0.011	0.004	1.002	0.001	0.001	1.000
P[5,2]	0.147	0.025	1.002	0.074	0.021	1.001
P[6,2]	0.028	0.028	1.000	0.038	0.036	1.000
P[1,3]	0.016	0.015	1.001	0.020	0.020	1.005
P[2,3]	0.031	0.007	1.000	0.026	0.007	1.001
P[3,3]	0.475	0.025	1.002	0.779	0.022	1.001
P[4,3]	0.014	0.004	1.002	0.003	0.002	1.001
P[5,3]	0.005	0.005	1.001	0.034	0.015	1.001
P[6,3]	0.028	0.028	1.001	0.036	0.035	1.005
P[1,4]	0.240	0.053	1.005	0.042	0.029	1.001
P[2,4]	0.002	0.002	1.001	0.047	0.009	1.001
P[3,4]	0.003	0.003	1.002	0.058	0.013	1.000
P[4,4]	0.945	0.008	1.003	0.965	0.007	1.001
P[5,4]	0.398	0.034	1.001	0.033	0.015	1.001
P[6,4]	0.147	0.059	1.002	0.185	0.075	1.002
P[1,5]	0.016	0.015	1.001	0.019	0.019	1.007
P[2,5]	0.103	0.011	1.003	0.002	0.002	1.002
P[3,5]	0.320	0.023	1.001	0.139	0.018	1.003
P[4,5]	0.023	0.005	1.001	0.023	0.005	1.001
P[5,5]	0.430	0.034	1.002	0.839	0.030	1.001
P[6,5]	0.089	0.047	1.000	0.036	0.034	1.001
P[1,6]	0.016	0.015	1.000	0.018	0.018	1.008
P[2,6]	0.045	0.008	1.000	0.003	0.002	1.001
P[3,6]	0.191	0.020	1.001	0.008	0.005	1.001
P[4,6]	0.002	0.002	1.000	0.005	0.003	1.001
P[5,6]	0.005	0.005	1.002	0.007	0.007	1.002
P[6,6]	0.649	0.078	1.001	0.595	0.092	1.000
P[1,7]	0.015	0.014	1.000	0.041	0.028	1.001
P[2,7]	0.018	0.005	1.002	0.011	0.004	1.001
P[3,7]	0.006	0.004	1.001	0.011	0.006	1.000
P[4,7]	0.004	0.002	1.001	0.001	0.001	1.001
P[5,7]	0.005	0.005	1.001	0.007	0.007	1.001
P[6,7]	0.029	0.029	1.001	0.074	0.051	1.000

P[i,j] indicates the transition probability from health state i (i=1..6) to health state j (j=1..7)