

# StepAhead Program Reduces Lower Limb Amputation Rates Among Diabetic ESRD Patients

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#### Introduction

- End-stage renal disease (ESRD) patients with diabetes are at high risk of lower limb amputations. Published data have found rates of 2.0 to 13.8 amputations per 100 patient-years.<sup>1-2</sup>
- StepAhead was an integrated diabetes mellitus care management program designed to enhance patient self-management and reduce the likelihood of unnecessary complications among diabetic ESRD patients.
- The StepAhead program had 4 goals:
- Improve rates of ESRD patients having physician-managed diabetes care.
- Ensure patients underwent a yearly eye examination to minimize diabetes-related eye problems and blindness.
- Educate patients regarding glucose management including verification of a working glucometer.
- Educate patients on the need for daily self-foot checks and verify monthly in-center foot examinations to identify lower limb ulcerations and infections.

#### Objective

We examined whether implementation of the 4 StepAhead educational and treatment initiatives was effective in reducing lower limb amputations among diabetic ESRD patients.

#### Methods

- The StepAhead program was piloted at 10 large dialysis organization (LDO) clinics on 10 February 2012. All ESRD patients with diabetes who received dialysis treatment at 1 of these clinics were eligible for analysis.
- Participants were propensity score matched to a cohort of diabetic ESRD control patients who were not enrolled in StepAhead for demographic comparisons.
- Patients were studied beginning at the time of enrollment in StepAhead and followed for 18 months. Patients were censored for StepAhead disenrollment, death, transfer of care away from the LDO, or discontinuation of dialysis.
- For StepAhead participants, amputation information was entered by staff into their electronic health records when such an amputation occurred during the study.
- Retroactive amputation histories were not available due to the manner in which patient data were captured by the clinical database.
- Quality assurance checks were run to ensure data regarding amputation rates were accurate.

#### Results

• Among StepAhead participants mean age was 62.9 years, 45.0% were female, 45.4% were black, 42.7% were Hispanic, 80.1% had Medicare as a primary insurer, and diabetes was the main cause of ESRD (70.7%) (Table 1).

Table 1. Baseline Comparisons of StepAhead Participants and Control Patients

	Controls (N = 447)	StepAhead Participants (N = 447)	p-Value
Age, years, mean ± SD	62.4 ± 12.7	62.9 ± 12.3	0.49
Female, n (%)	209 (46.8)	201 (45.0)	0.59
Race, n (%) White Black Hispanic Other	29 (6.5) 212 (47.4) 179 (40.0) 27 (6.0)	34 (7.6) 203 (45.4) 191 (42.7) 19 (4.3)	0.50
Vintage, months, n (%) < 12 12-23 24-47 > 48 missing	105 (23.5) 98 (21.9) 123 (27.5) 113 (25.3) 8 (1.8)	108 (24.2) 86 (19.2) 124 (27.7) 122 (27.3) 7 (1.6)	0.87
Primary insurance, n (%) Medicaid Medicare None Other VA	48 (10.7) 350 (78.3) 6 (1.3) 40 (9.0) 3 (0.7)	47 (10.5) 358 (80.1) 6 (1.3) 34 (7.6) 2 (0.5)	0.94
Dual Medicare/Medicaid eligibility, n (%)	198 (44.3)	193 (43.2)	0.74
Catheter use, n (%)	101 (22.6)	102 (22.8)	0.94
Charlson Comorbidity Index, n (%) 3 4 5 6 7 8+	11 (2.5) 54 (12.1) 127 (28.4) 89 (19.9) 93 (20.8) 73 (16.3)	10 (2.2) 56 (12.5) 111 (24.8) 98 (21.9) 94 (21.0) 78 (17.5)	0.88
Cause ESRD, n (%) Diabetes Other than diabetes Cause unknown	308 (68.9) 122 (27.3) 17 (3.8)	316 (70.7) 119 (26.6) 12 (2.7)	0.61
Heart failure, n (%)	47 (10.5)	45 (10.1)	0.83
Ischemic heart disease, n (%)	41 (9.2)	42 (9.4)	0.91
Hemoglobin A1c, % <sup>a</sup> < 6.5% 6.5-7.9% > 8% missing	150 (33.6) 112 (25.1) 45 (10.1) 140 (31.3)	150 (33.6) 102 (22.8) 57 (12.8) 138 (30.9)	0.60
Albumin, g/dL, <sup>a</sup> n (%) < 3.5 3.5-3.9 > 4	57 (12.8) 167 (37.4) 222 (49.7)	53 (11.9) 161 (36.0) 231 (51.7)	0.86
Phosphorus, mg/dL, <sup>a</sup> n (%) < 3.5 3.5-5.5 > 5.5 missing	60 (13.4) 233 (52.1) 92 (20.6) 62 (13.9)	60 (13.4) 225 (50.3) 99 (22.2) 63 (14.1)	0.94

Abbreviations: ESRD, end-stage renal disease; SD, standard deviation; VA, Veterans Administration. 

<sup>a</sup>Baseline measurement.

- Among the 18-month StepAhead participants (n = 228), 66.2% had 16-19 foot checks during follow-up (Table 2).
- During the 18 months of StepAhead, 11 program participants (2.2 patients amputated per 100 patient-years) underwent a total of 12 amputations (2.4 amputations per 100 patient-years).
- In the first 12 months of the program, rates of amputation were 2.5 patients per 100 patient-years and 2.7 amputations per 100 patient-years (Table 3).
- In the final 6 months of the program, rates were 1.6 patients per 100 patient-years and 1.6 amputations per 100 patient-years, respectively.
- Amputation rates for StepAhead participants were lower than those found in the literature (Figure 1).<sup>1-5</sup>

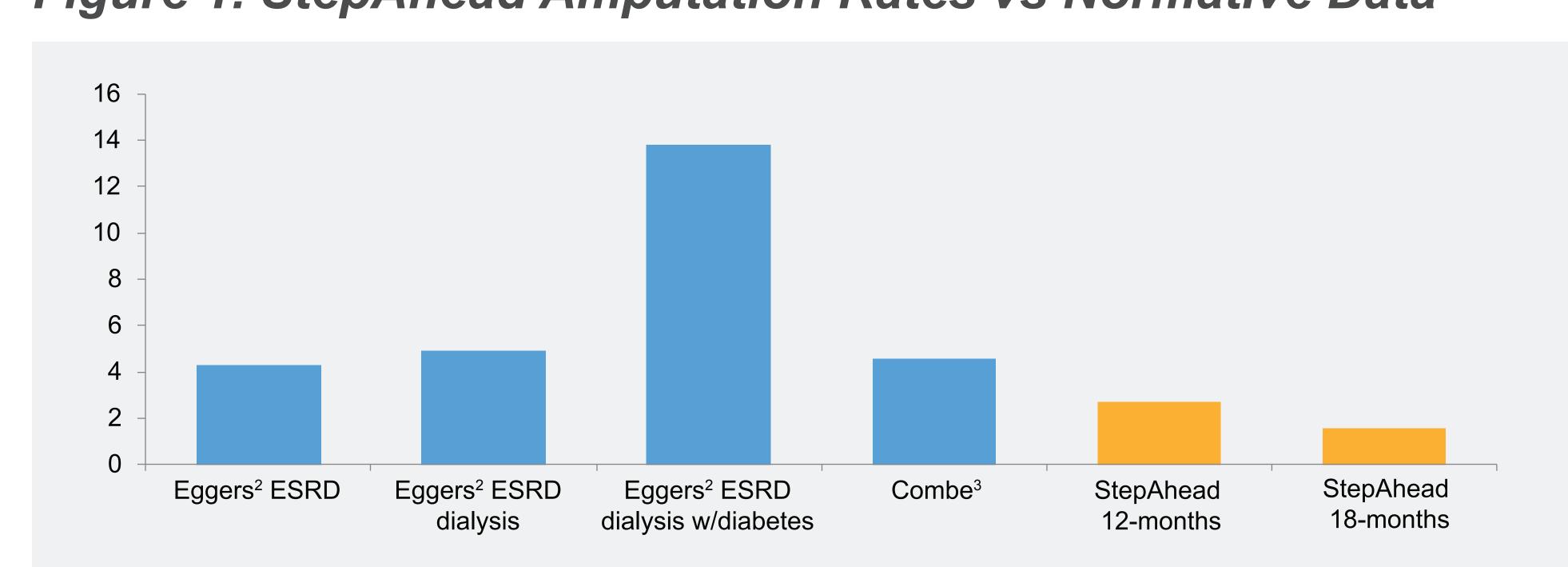
## Table 2. In-Center Foot Checks Among StepAhead Participants, Overall and at 18-Month Follow-up

No. Completed In-Center Foot Checks	All StepAhead Participants (N = 447)	18-Month StepAhead Participants (n = 228)	18-Month Cumulative %
0-5 during follow-up, mean (%)	133 (29.8)	12 (5.3)	5.3
6-10 during follow-up, mean (%)	78 (17.4)	15 (6.6)	11.9
11-15 during follow-up, mean (%)	79 (17.7)	50 (21.9)	33.8
16-19 during follow-up, mean (%)	157 (35.1)	151 (66.2)	100.0

Table 3. Amputation Rates Among StepAhead Participants

Follow-up months	At-risk time (pt-yr)	No. of Pt	Pt Amputated per 100 pt-yrs	No. of Amps.	Amps. per 100 pt-yrs
1-12	364	7	2.5	10	2.7
13-18	125	4	1.6	2	1.6
Overall	490	11	2.2	12	2.4
Abbreviations: Am	ps, amputations; No, nu	mber; Pt, patient	; pt-y, patient-year.		

Figure 1. StepAhead Amputation Rates vs Normative Data



Abbreviations: ESRD, end-stage renal disease; Pts, patients.

Note: Speckman followed 3,272 incident dialysis patients for 12 months and found an amputation rate of 4% among these patients. The risk for lower limb amputations increased to 6% among those end-stage renal disease patients with diabetes.

#### Conclusions

- Versus published normative data, rates of lower limb amputation among StepAhead enrollees was lower.
- In addition, improvement in amputation rates over time suggests that the full potential of the program in amputation avoidance may take time to be achieved and may not yet have been fully realized at the conclusion of the 18-month pilot.

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