

### Research Q3 Evidence Profile (Quantitative)

**Recommendation question 3:** Should support from a specialized interprofessional foot care team be recommended or not for persons at risk or living with DFUs?

**Recommendation 3.0:** The expert panel suggests that health service organizations implement a specialized wound care team to support persons at risk of or living with diabetic foot ulcers.

**Population:** Persons at risk of or living with DFUs

**Intervention:** Support from specialized interprofessional foot care team

**Comparison:** No support from a specialized interprofessional foot care team (i.e., standard care or care by one individual provider)

**Outcomes:** DFU occurrence/recurrence rate (critical); amputation rate (critical); DFU healing rates (critical); readmission rates (critical); patient satisfaction (critical) [not measured]

**Setting:** All health-care settings, including but not limited to: community care, outpatient care, and acute care

Table 1 – Quality details

Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
<b>DFU occurrence/recurrence rate</b> (measured using patient data as: number of DFUs per patient; ulcer rate at 1 to 3 years)											
1	Systematic review of 4 RCTs, cohort, and noncontrolled studies	Not serious <sup>a</sup>	Serious <sup>b</sup>	Not serious	Very serious <sup>c</sup>	Undetected	<b>Prevention of first-ever DFU<sup>d</sup></b> N=314  Ulcer incidence = 58  <b>Prevention of recurrent DFU</b> N=103  Ulcer recurrence = 35	<b>Prevention of first-ever DFU<sup>e</sup></b> N=308  Ulcer incidence=38  <b>Prevention of recurrent DFU</b> N=133  Ulcer recurrence=77	The controlled studies from this systematic review reported the use of a multidisciplinary team may prevent first-ever DFU and may prevent recurrent DFU.  Prevention of first-ever DFU: For every 100 people who received interprofessional foot care team, 1 less person will have an ulcer occurrence (ranges from 5 less to 5 more people RR 0.93, 95% CI 0.61-1.43).  Prevention of recurrent DFU: For every 100 people who received interprofessional foot care team, 24 less people will have an ulcer reoccurrence (ranges from 33 less to 12 less people RR 0.59, 95% CI 0.43-0.80).	⊕○○○ Very Low	(1)
<b>Amputation rate</b> (measured using patient data as major amputation rates <sup>f</sup> )											
1	Systematic review of 9 non-RCTs (before-after type/ quasi-	Serious <sup>g</sup>	Not serious	Not serious	Not serious	Undetected	N=1458 <sup>h</sup> Total amputations = 198	N=664 <sup>h</sup> Total amputations = 150	There was a trend towards a reduction in major amputation in the intervention group compared to the control group.  For every 100 people who received care from an interprofessional foot care team, 9 less	⊕⊕⊕○ Moderate	(2)

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Quality assessment							No. of participants		Effect	Certainty	Reference
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Intervention	Control			
	experimental studies)								people will have a major amputation (ranges from 6 less to 11 less RR0.60, 95% CI 0.50-0.73).		
<b>DFU healing rates</b> (measured using the Society for Vascular Surgery Wound, Ischemia, and foot Infection (WIFI) classification system, electronic chart data, or the tool used to measure outcome was not reported <sup>dii</sup> )											
1	Non-RCT	Very serious <sup>k</sup>	Not serious	Not serious	Very serious <sup>l</sup>	Undetected	N = 55 <sup>m</sup>	N = 64 <sup>m</sup>	Both intervention and control groups achieved comparable reduction in the total number of DFUs per patient, with 33.4 % reduction in the intervention group and 37.3 % reduction in the control group.  However, the intervention group had a 60.1% reduction in wound size compared to 52.4% reduction in control group after 5 months.	⊕○○○ Very low	(3)
3	Non-randomized single arm study	Very serious <sup>n</sup>	Not serious <sup>p</sup>	Not serious	Not serious	Undetected	N=333	N/A	Overall, three studies reported the use of a multidisciplinary team improved DFU healing rates.	⊕○○○ Very low	(4-6)
<b>Readmission rates</b> (measured using hospital in-patient enquiry with medical records)											
1	Non-randomized single arm study	Very serious <sup>o</sup>	Not serious	Not serious	Very serious <sup>q</sup>	Undetected	52 readmissions occurred in 512 participants after the intervention was conducted	N/A	The study reported the use of a multidisciplinary team decreased re-admission rates within 30 days.	⊕○○○ Very low	(7)
<b>Patient satisfaction [not measured]</b>											
N/A											

Table 2 – Individual Study Details

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
<b>DFU occurrence/recurrence rate</b> (measured using patient data as: number of DFUs per patient; ulcer rate at 1 to 3 years)						
(1)	Systematic review of 4 RCTs, cohort, and noncontrolled studies	Multiple countries (Brazil, Austria, Lithuania, France, Spain, Japan, USA, Tanzania)	<p>Integrated foot care was defined as care given by one or multiple collaborating professional treating patients on multiple occasions, possibly at multiple locations, with multiple interventions, also including referrals between different levels of health care.</p> <p>Integrated foot care differed between studies but always included foot treatment by an adequately trained professional, structured education, and prescription of appropriate footwear, with a regular examination of the patient and their feet.</p> <p>In most studied integrated foot care programmes, the key responsible professional was a podiatrist or chiropodist. N=314</p>	<p>No exposure to integrated foot care team or usual care N=308</p>	The controlled studies from this systematic review reported the use of a multidisciplinary team may prevent first-ever DFU and may prevent recurrent DFU.	LOW
<b>Amputation rate</b> (measured using patient data as major amputation rates)						
(2)	Systematic review of 9 non-RCTs (before-after type/ quasi-experimental studies)	Multiple countries (USA, Spain, Turkey, Saudi Arabia, Singapore)	<p>Multidisciplinary care team (MCT) was defined as a coordinated team of two or more physicians and/or hospital staff working together to care for a patient with diabetic foot disease.</p> <p>The most common members were a vascular surgeon, endocrinologist and podiatrist with four members comprising the MCT on average. N=1458 Total number of amputations = 198 RR [95%CI] = 0.61 [0.50, 0.75]</p>	<p>No exposure to MCT N=664 Total number of amputations = 150</p>	There was a trend towards a reduction in major amputation in the intervention group compared to the control group.	LOW
<b>DFU healing rates</b> (measured using the Society for Vascular Surgery Wound, Ischemia, and foot Infection (WIFI) classification system, electronic chart data, or the tool used to measure outcome was not reported)						
(3)	Non-RCT	Australia	<p>Patients with DFUs who were seen by a rapid-access interdisciplinary team (RAIT). RAIT is led by an endocrinologist, supported by a diabetes educator, a dietician, podiatrist, and a clinical psychologist. N=55</p> <p>Change in number of wound per patient over 6 months: June: 1.6 wounds November: 1</p>	<p>Usual care at general podiatry clinic (i.e., not seen by the RAIT). N=64</p> <p>Change in number of wound per patient over 6 months: June: 1.4 November: 0.7</p> <p>Baseline estimated wound volume (cm<sup>3</sup>), mean ± SD: 1.54 ± 6.73</p>	<p>Both intervention and control groups achieved comparable reduction in the total number of DFUs per patient, with 33.4 % reduction in the intervention group and 37.3 % reduction in the control group.</p> <p>However, the intervention group had a 60.1% reduction in wound size compared to 52.4% reduction in control group after 5 months.</p>	CRITICAL

Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
			Baseline estimated wound volume (cm <sup>3</sup> ), mean ± SD: 3.9 ± 13.1			
(5)	Non-randomized single arm study	USA	Multidisciplinary diabetic limb preservation service consists of vascular surgeons, surgical podiatrists, endocrinologists, wound care nurse, physician assistant, and prosthetist. Consultation from infectious disease, plastic surgery, and orthopedic foot and ankle physicians is obtained on a case-by-case basis as needed. N = 244 patients with 304 affected limbs	N/A	Wound healing of recurrent ulcers was reduced when a multidisciplinary team was used, compared to wound healing of initial ulcers.  <b>Post-intervention:</b> Healing after podiatric surgery alone: 44 % (n=135) Healing after combination of vascular and podiatric surgery: 12.5% (n=38) Healing after isolated vascular intervention: 11.8% (n=36) Healing after dedicated wound care: 31.3% (n=95)	CRITICAL
(4)	Non-randomized single arm study	Canada	Interprofessional Team composition at Toronto Regional Wound Healing Centre (TRWHC): a physician with training and extensive experience treating complex wounds, three nurses with advanced wound care expertise, a chiropodist trained in providing appropriate offloading, and a certified diabetes educator. N= 49	There was no control group, the results were compared pre-Community Care Access Centre (CCAC) care and post intervention TRWHC Care.	Wound closure rates improved following the interprofessional team's assessment and care.  <b>Pre-intervention:</b> Wound closure number (%): 9/30 (30.0%) <b>Post-intervention:</b> Wound closure number (%): 2/49 (4.08%)	CRITICAL
(6)	Non-randomized single arm study	Canada	At each visit, patients received personalized health education to optimize diabetes management and ulcer care by a multidisciplinary team composed of a counselor, a diabetes nurse educator, a wound-care nurse and a physician.  Patients were referred to infectious-disease specialists, dermatologists, endocrinologists, orthopedic surgeons, plastic surgeons and podiatrists, as indicated, throughout their ongoing care. N=40 Recurrent DFUs N= 17  Number of patients with recurrent DFUs healed at 52 weeks = 16 (94.1%)  Pre-existing DFUs N= 108 Number of patients with pre-existing DFUs healed at 52 weeks = 68 (63%)	N/A	Of the 40 patients for whom there were complete follow ups by a multidisciplinary team, 35 (87.5%) had healing of all DFUs by 52 weeks.  The unadjusted healing rate of recurrent ulcers (94.1%) was 31.1% higher than the unadjusted health rate of preexisting ulcers (63%).	SERIOUS

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Reference	Study Design	Country	Intervention Group Details	Control Group Details	Reported Effects/Outcomes	Risk of bias
<b>Readmission rates</b> (measured using hospital in-patient enquiry with medical records)						
(7)	Non-randomized single arm study	Ireland	<p>An acute diabetic foot pathway team assisted patients presenting with diabetic foot complications who required urgent admission to the hospital. The team included: infectious diseases (ID) specialists, endocrinologists, clinical microbiologists, tissue viability nurse specialists and physiotherapists.</p> <p>The pathway emphasized the requirement for rapid assessment, immediate appropriate antibiotic therapy, rapid imaging, an ID consultation and surgical procedures if required.</p> <p>Between Jan 2012 and March 2016: Number of patients: 189 Number of admissions: 419 91 of 419 patients (21.7%) were re-admitted between January 2012 and March 2016</p> <p>Between April 2016 and December 2019 Number of patients: 272 Number of admissions: 512 52 of 512 (10.1%) were re-admitted between April 2016 and December 2019</p>	N/A	The study reported re-admission rates within 30 days decreased from 21.7 to 10.1% following introduction of the acute diabetic foot pathway.	CRITICAL

**Acronyms**

CCAC = Community Care Access Centre

CI = confidence interval

DFU = diabetic foot ulcer

ID = infectious disease

ITT = intention to treat

IWGDF = International Working Group on the Diabetic Foot

MCT = Multidisciplinary care team

Non- RCT = non-randomized control trials

N.D. = no date

RAIT = Rapid-access interdisciplinary team

RCT = randomized control trial

SD = standard deviation

TRWHC = Toronto Regional Wound Healing Centre

## Evidence Profile Recommendation 3 - Diabetic Foot Ulcers: Prevention, Assessment and Management

### References:

1. Van Netten JJ, Raspovic A, Lavery LA, Monteiro-Soares M, Paton J, Rasmussen A, et al. Prevention of foot ulcers in persons with diabetes at risk of ulceration: A systematic review and meta-analysis. *Diabetes Metabolism Res.* 2024 Mar;40(3):e3652.
2. 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 & Clinical Practice.* 2020 Mar;161((Albright, Manohar, Murillo, Kengne, Delgado-Hurtado) The Dartmouth Institute for Health Policy&Clinical Practice, Geisel School of Medicine, Hanover, NH, United States):N.PAG-N.PAG.
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4. Somayaji R, Elliott JA, Persaud R, Lim M, Goodman L, Sibbald RG. The impact of team based interprofessional comprehensive assessments on the diagnosis and management of diabetic foot ulcers: a retrospective cohort study. *PLoS One.* 2017;12(9):e0185251.
5. Hicks CW, Canner JK, Mathioudakis N, Lippincott C, Sherman RL, Abularrage CJ. Incidence and risk factors associated with ulcer recurrence among patients with diabetic foot ulcers treated in a multidisciplinary setting. *Journal of Surgical Research.* 2020;246:243–50.
6. Roth-Albin I, Mai SH, Ahmed Z, Cheng J, Choong K, Mayer PV. Outcomes following advanced wound care for diabetic foot ulcers: a Canadian study. *Canadian journal of diabetes.* 2017;41(1):26–32.
7. Hurley H, Kellegher E, Gallen T, Cornally D, Williams N, Feeney E, et al. Development of a coordinated acute diabetic foot pathway for management of acute diabetic foot infection and ulceration. *Ir J Med Sci.* 2023 Feb;192(1):161–7.

### Explanations:

<sup>a</sup> The review was assessed using the ROBIS tool for systematic reviews, and had some risk of bias. Studies included in the review were assessed by the authors using the Cochrane ROB tool for RCTs; 3 studies had a low ROB, 1 study had a high ROB. We downgraded by 0.5.

<sup>b</sup> The review authors downgraded for inconsistency for integrated foot care on prevention of first-ever ulcer's evidence. We downgraded by 1.

<sup>c</sup> The total number of events was far less than the optimal number of 300 (first-ever ulcer events n= 74; recurrent ulcer events n= 112). We downgraded by 2.

<sup>d</sup> The review authors only provided sufficient level of detail to include the controlled trials in this evidence profile. Non-controlled trials from the review were not analyzed or appraised using GRADE.

<sup>e</sup> Data taken from supplementary document

<sup>f</sup> Amputation rate was defined as a measure of people who experienced high level amputation divided by people at risk for the event (e.g. the total population within that group) during specific time periods before and after MCT implementation.

<sup>g</sup> The systematic review was assessed using the ROBIS tool for systematic reviews, and had low risk of bias. Studies included in the review were assessed by the authors using the "Emergency Care Research Institute (ECRI) Before-After Scale tool", however we noted that this is not a widely used or validated tool. The systematic review also only used quasi-experimental studies, and there likely would be lack of control for confounding variables. The review authors were only able to conduct a meta-analysis using 9 of the 20 included studies in the review, due to missing outcome data. We downgraded by 1.

<sup>h</sup> Data was taken from Fig. 5.

<sup>i</sup> Measurement tool not reported for ulcer occurrence/ recurrence rate; Society for Vascular Surgery Wound, Ischemia, and foot Infection (WIFI) classification system for wound healing. Wound healing was defined as complete epithelialization with the restoration of sustained functional and anatomic continuity for 6 weeks after complete healing. Recurrent ulcers were defined as ulcers that formed on the same foot after complete wound healing was achieved.

<sup>j</sup> University of Texas Wound Classification System. Pre-existing ulcers were defined as nonhealing diabetic foot ulcers that were present at the first consultations with the patients at The Mayer Institute. Recurrent DFUs were defined as occurrences of new foot ulcers developed at any location during the 52-week follow-up period. DFUs were considered healed if there was complete epithelialization with restoration of functional integrity. Ulcers with incomplete follow up or missing information were assumed unhealed and were included in the analyses based on the worst-case scenarios.

<sup>k</sup> Based on quality appraisal using the ROBINS-I tool, the study had very serious risk of bias due to lack of control for confounding variables and missing data. We downgraded by 2.

<sup>l</sup> The total number of participants was much less than the optimal number of 800 (n=119). We downgraded by 2.

<sup>m</sup> 5-month results after are not clearly reported in the study. Data was taken from Fig. 3 & 4 through visual interpretation.

<sup>n</sup> Based on quality appraisal using the ROBINS-I tool, two studies had very serious risk of bias due to lack of control for confounding variables. Three studies had serious risk of bias due to lack of control for confounding variables, or classification of interventions. We downgraded by 2.

<sup>o</sup> All 3 studies showed a positive direction of effect, however two studies did not report the tool used to measure outcome. We downgraded by 0.5.

<sup>p</sup> Based on quality appraisal using the ROBINS-I tool, the study had very serious risk of bias due to lack of control for confounding variables and measurement of outcomes. It had no information regarding deviations from intended intervention or missing data. We downgraded by 2.

<sup>q</sup> The total number of events was far less than the optimal number of 300 (n=52). We downgraded by 2.

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<sup>†</sup> Once a patient achieved wound closure of their primary wound, they were no longer accounted for in the denominator as they were no longer followed by the TRWHC.