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Complete List of Authors:	Ahmajärvi, Kirsti; Helsinki University Central Hospital, Doctoral Programme in Populational Health and Department of General Practice and Primary Health Care Isoherranen, K; Helsinki University Central Hospital, Dermatological Department Venermo, M; Helsinki University Central Hospital, Vascular surgery Department
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Title page

A Cohort Study of Diagnostic Delay in the Clinical Pathway of Patients with Chronic Wounds in the Primary Care Setting

Authors:

1. Kirsti Ahmajärvi, MD, PhD Student, Specialist in General Practice, Special Competence in Wound Management
2. Kirsi Isoherranen, MD, PhD, Specialist in Dermatology and Allergology, Special Competence in Wound Management
3. Maarit Venermo, MD, PhD, Professor of Vascular Surgery

Address and position of each author:

University of Helsinki, P.O. Box 4, 00014 University of Helsinki

1. K Ahmajärvi, MD, PhD Student, Specialist in General Practice, University of Helsinki, Doctoral Programme in Populational Health and Department of General Practice and Primary Health Care, University of Helsinki and Helsinki University Hospital, Helsinki, Finland. Helsinki University Hospital, P.O. Box 250, 00029 Helsinki

2. K Isoherranen, MD, PhD, Specialist of Dermatology and Allergology, Skin and Allergy Hospital, Meilahdentie 2, 00029 HUS, Finland.

3. M Venermo, MD, PhD, Vascular Surgeon, Professor of Vascular Surgery, Head of the Department, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

Affiliations:

1. K Ahmajärvi, MD, PhD Student, University of Helsinki, Doctoral Programme in Populational Health and Department of General Practice and Primary Health Care, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

2. K Isoherranen, MD, PhD, Department of Dermatology and allergology, University of Helsinki and Inflammation center, Helsinki University Hospital, Helsinki, Finland

3. M Venermo, MD, PhD, Vascular Surgeon, Professor of Vascular Surgery, Head of the Department, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

Corresponding Author: Kirsti Ahmajärvi

Correspondence to: kirsti.ahmajarvi@helsinki.fi

ORCiD: Kirsti Ahmajärvi: https://orchid.org/0000-0002-0253-2567

ORCiD: Kirsi Isoherranen: https://orcid.org/0000-0002-0253-2567

ORCiD: Maarit Venermo: https://orcid.org/

Kirsti Ahmajärvi is the responsible guarantor of content and has contributed to the planning, conduct, and reporting of the work described in the article.

Kirsi Isoherranen has contributed to the planning and reporting of the work described in this article.

Maarit Venermo has contributed to the following parts in this study: Design of the study, data analysis and interpretation, revisions to scientific content of the manuscript, review and editing of the final manuscript.

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Keywords: chronic wound, leg ulcer, foot ulcer, wound management, wound aetiology, primary care, diagnostic process, diagnostic delay, clinical pathway

Words 4632

Abstract

Objectives: Exact wound diagnosis is essential for successful wound management and a holistic care of the patient suffering from a wound. Wound management has been traditionally seen as a nursing area, but this can lead to considerable delays in wound diagnostics. A diagnostic delay has been recognised as an element of diagnostic error, which, in turn, affects patient safety. The aim of this cohort study was to examine diagnostic delays of chronic wound within primary care.

Setting: A specialised diagnostic unit, a wound care team, was established in the primary health care with the objective of reducing diagnostic and treatment delays in primary care.

Participants: The data consists of 197 consecutive patients attending their first appointment with the wound care team in 2016. The collected data included basic demographics, information about the clinical pathway, including doctor's appointments in primary and specialised care, as well as the ICD-10 diagnostic codes.

Primary and secondary outcome measures: The diagnostic delays were calculated in days and divided into three groups: 1) patient-related delay, 2) diagnostic delay and 3) organisational delay.

Results: The median duration of a patient-related delay was two days (IQR 0-14), whereas a physician's first evaluation was performed at a median of 8 (1–32) days from wound appearance and the correct diagnosis by the wound care team was established in a median of 57 (33-100) days. The organisational delay from first contact to diagnosis was a median of 41 (22–80) days. Only one in three patients had a diagnostic delay of less than 4 weeks.

Conclusions: According to this study, the diagnostic delay occurs within primary care, as an organisational delay from first contact to correct diagnosis It is possible to arrange an optimal pathway of care in which a holistic wound care process starts within primary care.

A COHORT STUDY OF DIAGNOSTIC DELAY IN THE CLINICAL PATHWAY OF PATIENTS WITH CHRONIC WOUNDS IN THE PRIMARY CARE SETTING

Introduction

Chronic wounds pose a significant burden to health care, constituting roughly 2%–6% of all health care costs (1-3). According to a recent study in the UK, the annual prevalence of wounds increased by 71% between 2012/2013 and 2017/2018 and patient management costs increased by 48% in real terms (4). In addition to costs, chronic wounds cause substantial suffering at the individual level, leading to an impaired quality of life, social isolation and mental health problems (5-7). Wound management can be successful only when the wound is correctly diagnosed and treated accordingly (8,9). Wound care has been traditionally viewed as measures related to the assessment of the wound bed, which can obscure the importance of the holistic care of the patient (10).

In many European countries, wound patients are first seen in primary care by general practitioners (GPs) or nurses (11). This poses a significant challenge to primary care: wound patients should receive a timely evaluation by a qualified health care professional who can make the correct diagnosis, plan holistic treatment and make the necessary referrals (12). This process should aim to avoid diagnostic error, which has been recognised by the World Health Organization (WHO) as a global challenge to patient safety (13). Diagnostic error includes an incorrect or delayed diagnosis, which leads to patient harm or to inappropriate or delayed treatment. The diagnostic errors mainly occur within primary care or at the emergency department, where physicians lack the appropriate tools and sufficient time to make accurate decisions (14, 15).

In 2013, a special wound care team was established in the primary health care system of the Helsinki area. The wound care team consists of a wound care nurse and a general practitioner specialised in wound care. This team has the possibility to consult a podiatrist and/or vascular surgeon. Patients are referred to a wound care team consultation from all primary care units: health centres, home care units and nursing homes. The instructions for the primary care personnel were to react early and refer patients suffering from a non-healing wound within (2–)4 weeks of wound appearance in order to have the wound appropriately diagnosed. The main focus of the wound care team was to discover the correct diagnosis as early as possible and, thereafter, to initiate proper treatment accordingly.

The purpose of this study was to evaluate the delay in the diagnostic process in the clinical pathway of wound patients who were referred for a consultation by the wound care team during 2016. The delays were divided into system-related and patient-related delays.

Material and methods

This prospective cohort study analysed the characteristics and medical history of 197 consecutive patients who visited the wound care team in primary health care during 2016. The information was collected at the first wound care team appointment.

Data were collected from electronic patient records. The collected data consisted of patients' background factors (sex, age, comorbidities, medication, previous wounds, state of mobility and living standards, need of home care, smoking, blood sugar levels and lipids), as well as the date of wound appearance, the date of the patient's first contact with a primary care unit and physician's appointment, the date of consulting the wound care team, and the date of admission to a specialist care unit if needed. In order to analyse the diagnostic process, additional information was collected on signs of infection and bacterial swab results, on whether the ankle brachial index (ABI) was measured or pulse palpation occurred, or whether neuropathy was detected with a monofilament test. Observations of oedema and any blood test analyses regarding the wound were also recorded. Furthermore, information was gathered from radiological examinations, if performed, as well as any further investigations within specialist care, such as toe pressure and angiography results. The treatment plan was evaluated and compared to the diagnostic methods and the ICD-10 code.(Supplementary Table 1)

Delays were calculated at different points of the care pathway, starting from wound appearance. The different types of delays included: 1) patient-related delay (time from wound appearance to the patient's first contact with health care providers), 2) diagnostic delay (time from the onset of the wound to the first physician's appointment where the initial diagnosis was made), and 3) organisational delays within primary care in arriving at the correct diagnosis and treatment (from the first contact with the primary health care unit to the wound care team consultation). Some patients needed a referral to a specialist consultation, and this delay was also considered.

Diagnostic codes were collected as ICD-10 codes and we compared to the diagnoses made by the primary care physician, by the wound care team physician and by the specialist. As the number of different diagnostic codes was high, we categorised the diagnoses into ten groups (Table 1, Figures 1a and 1b). In the grouping process, we also included, in addition to the diagnostic code, information on how the wound had appeared and which diagnostic tools had been used to arrive at the specific conclusion and treatment plan.

Table 1. Categorisation and diagnostic variation in the clinical pathway of a patient with a wound.

Diagnostic categories	Primary care physician (n = 129)	Wound care team physician (n = 197)	Specialist care physician (n = 110)
No diagnosis*	26	2	1
Arterial wound	4	16	26
Venous or oedematous ulcer	15	57	17
Diabetic foot ulcer	4	24	15
Pressure ulcer	12	29	9
Post-traumatic wound	16	23	3
Atypical wound	0	8	7
Mixed-aetiology ulcer	0	7	3
Infectious wound	42	11	10
Foot malformation or pressure ulcer	0	7	1
Wound of unspecified aetiology	36	13	19

*The category was defined as 'no diagnosis' when a patient had been seen by a physician but there was no ICD-10-coded diagnosis in the patient records.

In order to avoid bias caused by outliers, 16 patients whose wound had persisted for over 365 days prior to the wound team consultation were excluded from the delay analysis.

Patient and public Involvement

No patient or public involvement has been occurred in planning, managing, designing or carrying out this research.

Results

A total of 197 patients were included in the study. The mean age was 71 years, and 106 (53,5%) patients were female. The basic demographics and risk factors of the patients are reported in Tables 2-3.

Table 2. Basic demographics.

	Female(n)	%	Male (n)	%	Total (n)	%
Sex	106	53.8	91	46.2	197	100
Age (y)						
Mean	78	39.6	69	97.2	71	36.0
Median	80	40.6	73	37.1	41	20.8
Mobility (n)						
walking	38	19.3	56	28.4	94	47.7
walking with assistance device	33	16.8	20	10.2	53	26.9
walking with device only indoors	16	8.1	5	2.5	21	10.7
wheelchair	11	5.6	8	4.1	19	9.6
bedridden	8	4.1	2	1.0	10	5.1
Residence (n)						
home	57	28.9	73	37.1	130	66.0
home with home care	30	15.2	12	6.1	42	21.3
assisted living facility	14	7.1	5	2.5	19	9.6
24/7 care nursing home	5	2.5	1	0.5	6	3.0

Table 3 Description of the sample (n = 197, % of total) in individuals; comorbidities and risk factors.

Comorbidities	Female (n)	%	Male (n)	%	Total (n)	%	p-value*
Hypertension	60	30.5	50	25.4	110	55.8	
Heart failure	25	12.7	11	5.6	36	18.3	p = 0.044
Ischaemic heart disease	13	6.6	10	5.1	23	11.7	
Atrial fibrillation	37	18.8	24	12.2	61	31.0	
Respiratory condition	27	13.7	11	5.6	38	19.3	
Cancer	14	7.1	14	7.1	28	14.2	
Mental Health condition	9	4.6	9	4.6	18	9.1	
Dementia/memory disorder	25	12.7	9	4.6	34	17.3	p = 0.013
Diabetes	30	15.2	47	23.9	77	39.1	p < 0.001
Peripheral arterial disease	16	8.1	24	12.2	40	20.3	p = 0.042
Kidney malfunction	12	6.1	15	7.6	27	13.7	
Rheumatoid arthritis	15	7.6	6	3.0	21	10.7	p = 0.091
Liver malfunction	0	0.0	6	3.0	6	3.0	p = 0.007
Spinal stenosis	5	2.5	3	1.5	8	4.1	
Gout	3	1.5	8	4.1	11	5.6	p = 0.064
Haematological condition	5	2.5	6	3.0	11	5.6	
Chronic pain disorder	2	1.0	0	0.0	2	1.0	
Urinary condition	4	2.0	10	5.1	14	7.1	p = 0.045
Cerebrovascular disorder	15	7.6	13	6.6	28	14.2	
Dermatological disease	3	1.5	2	1.0	5	2.5	
Musculoskeletal disorder	21	10.7	7	3.6	28	14.2	p = 0.018
No comorbidities	3	1.5	4	2.0	7	3.6	

Risk factors	Female (n)	%	Male (n)	%	Total (n)	%	p-value*
Previous wounds	46	23.4	50	25.4	96	48.7	
Previous DVT	9	4.6	1	0.5	10	5.1	p = 0.020
venous insufficiency	9	4.6	7	3.6	16	8.1	
chronic oedema	3	1.5	2	1.0	5	2.5	
chronic cellulitis	10	5.1	5	2.5	15	7.6	
previous amputation	4	2.0	1	0.5	5	2.5	
Smoking (n)	13	6.6	28	14.2	41	20.8	p = 0.001
Drug abuse	2	1.0	5	2.5	7	3.6	p = 0.010
Alcohol abuse	3	1.5	11	5.6	14	7.1	
Overweight (BMI 24–30)	59	29.9	62	31.5	121	61.4	
Obesity (BMI over 30)	26	13.2	29	14.7	55	27.9	
High cholesterol (diagnosis)	22	11.2	23	11.7	45	22.8	
LDL over 3.0	23	11.7	19	9.6	42	21.3	
Joint malformation	8	4.1	3	1.5	11	5.6	p = 0.010
Neuropathy (diagnostic coded)	8	4.1	18	9.1	26	13.2	p < 0.001
Neuropathy (monofilament test posit.)	32	16.2	54	27.4	86	43.7	
MRSA	2	1.0	6	3.0	8	4.1	p = 0.048

hemiplegia	2	1.0	2	1.0	4	2.0	
HbA1c(n=153)							
Mean (SD)	43 (12.9)		49 (16.8)		46(15.1)		p = 0.018~
Median (IQR)	40		43		41(37 - 52)		
BMI(n=178)							
Mean(SD)	27.4 (8.2)		29.0 (6.2)		28 (7.4)		
Median	26		28		26 (23 - 32)		
fP-Kol-LDL(n=169)							
Mean(SD)	2.5 (0.83)		2.4 (0.86)		2.5 (0.84)		
Median	2.4		2.3		2.4 (1.8-3.0)		
fP-Gluk(n=193)							
Mean(SD)	6.0 (1.8)		7.3 (3.4)		6.6 (2.7)		p = 00.1~
Median	5.8		6.7		5.9 (5.3-6.9)		

*Pearsons chi-squared, difference between female and male patients

~One-way ANOVA test

The majority of the patients were living at home (n = 172; 86.9%) either without any support (n = 130) or with home care (n = 42). The patients' living status is presented in Table 2. Almost half of the patients had had wounds earlier (48.7%). As regards comorbidities, 39.1% had diabetes, 11.7% ischemic heart disease, 17.3% memory disorders and 9.1% a mental health condition. Only 3.6% had no comorbidities. Overweight (61.4%), obesity (27.9%) and neuropathy (43.4%) were relatively common. Venous insufficiency or a previous deep venous thrombosis had been diagnosed in only 13.2%. As can be seen in Tables 3 and 4, the patients had several co-morbidities and heterogenous medications. Almost half of the patients used analgesics (44.7% NSAIDs or paracetamol and 15.2% opioids), whereas different psychopharmaceuticals were used by 11.7%–17.8% of the patients.

Table 4. Description of the sample (n = 197) in individuals; medication.

Medication	Female (n)	%	Male (n)	%	Total (n)	%	chi-square
Cardiac and vessel medicine							
Anticoagulant	41	20.8	26	13.2	67	34.0	p = 0.164
Antithrombotic	29	14,7	28	14.2	57	28.9	
b-blocker	57	28.9	41	20.8	98	49.7	
Diuretic	45	22.8	32	16.2	77	39.1	
Ca-blocker	27	13.7	31	15.7	58	29.4	
ACE-blocker	38	19.3	47	23.9	85	43.1	p = 0.018
Statin	40	20.3	35	17.8	75	38.1	
Diabetes medicine							
Oral diabetes medicine	16	8.1	21	10.7	37	18.8	p = 134
Insulin	12	6.1	30	15.2	42	21.3	p < 0.001
Psychopharmaceuticals							
Dementia medicine	16	8.1	6	3.0	22	11.2	p = 0.066
Antidepressant	14	7.1	11	5.6	25	12.7	
Benzodiazepine	13	6.6	10	5.1	23	11.7	
Sleeping pills	23	11.7	12	6.1	35	17.8	p = 0.135
Analgesia(mild)	57	28.9	31	15.7	88	44.7	p = 0.008
Opiates	18	9.1	12	6.1	30	15.2	
Immune system medicine							
Cancer medicine	2	1.0	3	1.5	5	2.5	
Immunosuppressive	11	5.6	4	2.0	15	7.6	p = 0.124
Cortisone per oral	12	6.1	4	2.0	16	8.1	p = 0.083
Cortisone cream	4	2.0	0	0.0	4	2.0	p = 0.064
Supplements							
Thyroxin	16	8.1	3	1.5	19	9.6	p = 0.006
Ca-supplement	46	23.4	16	8.1	62	31.5	p < 0.001
Folic acid	7	3.6	3	1.5	10	5.1	
B12-supplement	11	5.6	12	6.1	23	11.7	
Vitamin D suppl.	44	22.3	22	11.2	66	33.5	p = 0.013
Nutrition suppl.	6	3.0	2	1.0	8	4.1	
Mg suppl.	7	3.6	4	2.0	11	5.6	
K suppl.	11	5.6	9	4.6	20	10.2	
Other							
Inhaler/nebulizer	26	13.2	16	8.1	42	21.3	
Proton pump inhibitor	39	19.8	20	10.2	59	29.9	p = 0.030
Urine medicine	8	4.1	12	6.1	20	10.2	
Skin cream	19	9.6	10	5.1	20	10.2	p = 0.190

Diagnostics

Forty-two (21.3%) patients were not seen by a primary care physician before they visited the wound care team, meaning that the diagnostic process was not even started before this visit. Of the 155 patients who had been seen by a physician prior to the wound care team, 129 (83.2%) had a recorded diagnosis code (ICD-10), while 26 (16.8%) patients remained undiagnosed. Thus, 34.5% of the patients (n = 68) received their first diagnosis by the wound care team.

Out of the patients who were seen by a primary care physician, 85 (58.8%) had no delay (median 0 days), meaning that the patients visited an emergency room and were seen by a physician immediately. The diagnoses for these patients mainly comprised infectious wounds (n = 30, 35.3%) and wounds with no specific cause (n = 21, 24.7%), while a diagnostic code was not recorded for 10.6% (n = 9). Hence, 15 patients had traumatic wounds and saw the physician at an acute appointment.

Of those patients who saw a primary care physician (n = 155), 36.2% (n = 56) had clinical signs of infection according to the patient records. However, as many as 94 (60.6%) patients were treated with antibiotics, and 82 (52.9%) had a bacterial swab taken.

Of the 129 patients who had a diagnosis before the first appointment with the wound care team, the same diagnosis was made by the team and the primary care physician in 59 (45.7%) of the cases. The concordant diagnoses most often entailed pressure ulcers, infectious ulcers, as well as venous and post-traumatic ulcers. Specialist care was received by 111(%) patients. The same diagnosis (ICD-10) was made by all three points in the clinical pathway in only 24 (12.2%) cases, and the majority of these comprised infectious ulcers, followed by a venous aetiology and wounds without a specific diagnosis. (Table 5.)

Table 5. Differentiation of the diagnoses when they remained unchanged or were revised over the clinical pathway.

	Diagnoses that remained unchanged...			Diagnoses that were revised.	
Categorised diagnostic groups	within primary care	throughout the entire clinical pathway	by wound care team and specialist care	Primary care physician's diagnosis	Wound care team physician's diagnosis
Arterial wound	0	0	16	4	7
Venous or oedematous ulcer	13	5	17	2	24
Diabetic foot ulcer	2	1	13	2	11
Pressure ulcer	11	3	9	1	8
Post-traumatic wound	15	3	3	0	2
Atypical wound	0	0	7	0	4
Mixed-aetiology wound	0	0	2	0	3
Infectious wound	10	8	9	32	1
Foot malformation or pressure ulcer	0	0	1	0	5
Wound of unspecified aetiology	8	4	6	27	3

Of the patients who visited a specialist, the same diagnosis was made by the wound care team physician and the specialist in 75.5% of the cases (Table 5 and 6). The concordant diagnoses most often comprised diabetic foot ulcers (20.5%), arterial ulcers (19.3%) and venous or oedematous ulcers (15.7%). In the remaining 24.6% (n = 27) of the patients, the diagnosis made by the wound care team was revised in specialist care, mostly comprising arterial ulcers (40.7%) that were usually referred for further investigations with a suspicion of an arterial wound. The ulcers that turned out to be arterial wounds were diagnosed by the wound care team as diabetic foot ulcers (14.8%), wounds of mixed aetiology (18.5%), foot malformations (14.8%) and oedematous ulcers (37.0%).

Post-traumatic wounds were categorised into one category. In the primary care setting, there were 16 post-traumatic ulcers, 15 of which were assessed in the emergency room (ER).

Table 6. Diagnostic differentiation through the treatment pathway.

	The same diagnosis~ throughout entire treatment pathway	The same diagnosis within primary care~~~	The same diagnosis by wound care team and specialist
1 = the same	24	60	83
0 = different	47	67	27
total	71	127	110
% of diagnosed*^ patients	21,8	47,6	75,5
% of 197 (whole sample)	12,2	30,5	42,1

~ treatment pathway: primary care physician, wound care team (physician) and specialist care.
~~~primary care physician and wound care team (physician)
*155 patients visited a doctor in primary care before the appointment with the wound care team, but only 126 patients were diagnosed.
^110 patients were diagnosed in specialist care.
~~~

Delays

The median time from wound appearance to the first health care contact was 2 days (IQR 0–14 days, range 0–351 days) and from wound appearance to the first evaluation by a physician 8 days (IQR 1–32 days, range 0–314 days). The majority of the patients had their first health care contact at the emergency department where a physician also examined the patient, or at the district nurse's office at a health centre with the possibility of an immediate physician's consultation. The median time from the onset of the wound to the first wound care team appointment was 57 days (IQR 33–100 days, range 2–358 days). The median time between the first health care contact and the wound care team appointment was 41 days (IQR 22–80 days: range 1–484 days). Only one in three patients (n = 61) had an organisational delay of less than 4 weeks between the first contact with health services and the appointment with the wound care team.

Half of the patients (n = 113, 57.4%) were referred to a secondary health care unit to be seen by a specialist, most often by a vascular surgeon (n = 67), followed by a plastic surgeon (n = 43) and a dermatologist (n = 13). Twenty-one (18.6%) patients were referred to two or more specialists. The median delay from the first appointment with the wound care team to the appointment with the secondary health care specialist was 21 days (IQR 8–55, min–max -58–235; range 293 days).

The median time from the appearance of the wound to the final diagnosis was 57 days (IQR 33–101; min–max 2–358; range 356 days).

The delays in different the subgroups are presented in Table 7.

Table 7. Delays in different subgroups. Figures are presented as medians (IQR; Min–Max; Range)

Delays are calculated and analysed with the inclusion criterion 'wound appearance within 365 days prior to wound care team appointment'.

	n	Wound appearance - first contact to health care	Wound appearance to first physician evaluation	Wound appearance to wound care team	Delay from first contact to wound care team (organizational delay within primary care)	Delay Wound care team to specialist care	Mann-Whitney-U
All patients	182	2 (0–14;0–351;351)	8(1–32;0–314;314)	57(33–101;2–358;356)	42(22–80;1–484;483)	21(7–52;-58–252;414)	
Male	81	3 (0–24;0–351;351)	9(1–37;0–314;314)	69(37–111;2–358;356)*	44(23–85;2–484;482)	23(3–48;-58–235;293)	*p = 0.058
Female	101	1 (0–8;0–295;295)	8(1–24;0–295;295)	54(30–96;2–306;304)*	41(22–76;1–264;263)	20(8–58;0–176;176)	
Age under 65 y (1)	46	6 (1–27;0–298;298)*	9(3–30;0–142;142)	62(36–100;11–320;309)	37(22-76;6–382;376)	28(14–48;1–182;181)	*1 vs 2; p = 0.005
Age 65–80 y (2)	62	0 (0–14;0–258;258)*	10(0–38;0–314;314)	61(41–106;10–337;327)	49(25–88;4–264;260)	16(2–50;0–235;235)	*1 vs 3; p = 0.003
Age over 80 y (3)	74	1 (0–8;0–351;351)*	7(1–32;0–295;295)	53,5(30–98;2–358;356)	40(22–78;1–484;483)	16(6–56;-58–167;225)	
DM+	72	1 (0–15;0–142;142)	10(1–37;0–142;142)	59(36–102;2–324;322)	45(26–75;2–245;243)	14(3–48;0–235;235)	no statistical
DM-	110	2 (0–13;0–351;351)	7(1–32;0–314;314)	56(31–101;4–358;354)	40(22–84;1–482;483)	26(8–56;-58–167;225)	difference
Living at home	160	2 (0–15;0–351;351)	9(1–33;0-314;314)	57(33–102;2–358;356)	42(22–83;1–382;381)	20(5–48;0–235;235)*	*p = 0.010
Living in institution	22	1 (0–8;0–295;295)	3(0–14;0–295;295)	55(34–86;7–306;299)	43(24–72;7–484;477)	56(16–143;-58–176;234)*	
Walking; outdoors	134	3 (0–15;0–351;351)*	8(1–27;0–246;246)	56(33-97;4–358;354)	40(22–76;1–382;381)	22(6–56;-58–235;293)	*p = 0.047
Not-walking; staying indoors	48	0 (0–5;0–298;298)	9(1–55;0–314;314)	71(33–108;2–337;335)	54(24–94;2–484;482)	16(7–46;0–182;182)	
Delay before wound care team under 28 days	61	6 (0–20;0–351;351)*	7(3–24;0–295;295)	26(19–41;2–358;356)*	18(12–22;1–28;27)	22(4–42;0–167;167)	*p < 0.001
Delay before wound care team over 28 days	121	0 (0–8;0–258;258)	9(0–34;0–314;314)	73(51–112;29–337;308)	70(42–101;29–484;455)	20(7–55;-58–235;293)	
Unchanged diagnosis (PC–WT–spec.)	20	3 (2–12;0–246;246)	7(3–19;0–246;246)	51(32–80;5–267;262)	35(20–74;2–186;184)	23(8–45;0–89;89)	
Different diagnosis	43	1 (0–17;0–258;258)	8(0–42;0–314;314)	71(37–111;4–337;333)	57(30–89;1–245;244)	18(7–98;0–235;235)	
The same DG within primary care	55	2 (0–7;0–246;246)	3(1–18;0–246;246)	52(31–78;5–267;262)*	40(20–71;2–186;184)	33(9–56;0–176;176)	*p=0.042
Different DG	61	1 (0–24;0–258;258)	17(1–56;0–314;314)	73(37–126;4–337;333)	53(31–98;1–245;244)	15(7–64;0–235;235)	

Discussion

It is well-known that an early diagnosis of the underlying cause of a chronic wound is essential for wound healing and for avoiding amputations (8, 16, 17). However, there are only a few studies

describing the importance of wound diagnosis and the deleterious effects of diagnostic delays (18-20). In the current study, we investigated the diagnostic processes and delays in wound care in the Helsinki area. The patients' first contact with health care services after wound appearance was prompt, the median delay being only 2 days. In stark contrast, it took 57 days from the appearance of the wound before the patient was seen by the wound care team for the first time. In our material, only 31.0% of the patients visited the wound care team within 4 weeks of the first health care appointment. This caused a significant delay in reaching the correct diagnosis of the wound. We also discovered that only 65.5% of all patients had a recorded wound diagnosis before the first wound care team appointment and that this diagnosis matched the final diagnosis in approximately 50% of the cases. Accordingly, in European countries, the delay in diagnosing diabetic foot ulcers (DFU) was over 3 weeks in 21%–34% of the patients. The shortest average time from event to diagnosis was 10 days in the UK, 14 days in Spain and France, and 20 days in Germany. (12)

In Finland, wound patients are evaluated and treated mainly during primary care appointments, including home care and nursery homes (21). In the mentioned European countries, the health care professionals who participate in the diagnostic process vary considerably. In the UK, only 6% of GPs completely agreed that the care and management of DFUs is the GP's responsibility, and 22% did not diagnose DFUs. Instead, in 27% of the cases, district nurses made the diagnosis. In the UK, the approach seems more often to be multidisciplinary, as 49% of the GPs referred patients to a podiatrist if needed. In all four countries, GPs were able to refer DFU patients to specialised multidisciplinary clinics. (22)

In the UK, DFUs were diagnosed by a GP in only 45% of the cases, and most of the wounds were diagnosed by a district nurse or practice nurse (12).

The optimal treatment pathways for wound patients include patient surveillance and an early detection of wound healing problems. Errors in the pathway may lead to delays and, consequently, even fatal errors, such as amputations, in some patients. (17)

We took a closer look at the ICD-10 codes assessed by the primary care physicians, wound care team physician and specialists and found that they differed from each other significantly. This highlights the complexity of wound diagnostics. Surprisingly, only 12.2% of the patients had the same diagnosis throughout the whole pathway of care, and these mostly comprised infectious wounds. Based on our data, we assume that there was a significant overdiagnosis of infections in primary care, since an infectious wound was diagnosed in 32.6% of the cases and antibiotics were prescribed for 63.2% of the patients in the primary care setting. Similar results have been obtained in Sweden, where the use of a national wound register diminished the use of antibiotics (24). Evidence of difficulties in the diagnostics of wound infections is also found in a study of GPs recognising and treating wound infections – according to the results, GPs mostly desired further knowledge about when to start or stop treatment (81%–82%), about topical antimicrobials (80%–68%) and about when to prescribe antibiotics (82%–95%) (24).

Another diagnostic challenge was the diagnosis of an ischaemic wound and diabetic foot ulcer in primary care. Only four diabetic and arterial ulcers were diagnosed in primary care. In contrast, the wound care team diagnosed a DFU in 54 patients, and 26 patients were referred to a specialist

when an ischaemic wound was suspected. This problem is also detected in a multi-centre study performed in four European countries. The researchers found that, even though GPs described neuropathy and peripheral arterial disease as cofactors in the DFU development, they investigated DFUs with additional tests in only half of the cases; this entailed monofilament tests in 21%–43% and, more often, pulse palpation or the measurement of the ankle brachial index in 78%–90% of the cases, but diabetic foot infection (DFI) was tested in only 7%–20% of the investigated cases. (11)

Our main finding was that there was an organisational delay in reaching a timely diagnosis. The time between wound appearance and the first contact with a physician was adequate, the median being 8 days, and two-thirds (58.8%, n = 85) of the patients had their first evaluation at the first contact with health services. This means that a physician's examination was mostly available at the emergency room or as a rapid consultation during a nurse's appointment at the health centre. However, our study shows that, among these patients, the initial physician's evaluation very seldom leads to a correct diagnosis and treatment.

Regarding wound patients, emergency room assessment should include the three most important and acute aetiologies, such as infection, ischaemia and diabetes (25), but otherwise the emergency room might not be the optimal setting for diagnosing wounds.

Post-traumatic ulcers could be a subgroup of oedematous leg ulcers due to the same management approach, namely compression therapy, which should be assessed immediately after vascular/arterial causes have been ruled out. Hence, according to the present data, oedematous and post-traumatic ulcers accounted for 40.6% of all the ulcers and were treated with compression.

We found that the wound diagnostic process was good enough in the wound care team, as the diagnosis did not change for 75.5% of the patients who were referred by the team to specialist care. In the remaining 24.5%, in whom the diagnosis made by a specialist differed from the diagnosis made by the wound care team, the final diagnosis was confirmed using diagnostic tools that were not available in the health centre. In these cases, however, the wound care team often had a default diagnosis to base the referral on, and specialist care then responded to this idea, most often leading to the correct treatment. Indeed, the referral was very useful for these patients.

On the other hand, there were ordinary delays in receiving a specialist evaluation, as the median delay was 21 days, where the largest differences were between the subgroups of patients living in institutions and those living at home. This might be explained by the advance care planning among nursing home residents. However, previous studies propose delays of less than two weeks in diagnosing arterial ulcers and DFUs to avoid leg losses (17).

Previous studies suggest that diagnostic errors are often preceded by common symptoms, followed by common diagnoses (26, 27). Studies have shown that the most frequent error is "premature closure", meaning 'the tendency to stop considering other possibilities after reaching a diagnosis' (28, 29). In the UK, diagnosis- and assessment-related incidents were the highest causes of patient harm (26). As a conclusion, the ability to utilise differential diagnostic methods is

key when diagnosing wound aetiologies. There is always a danger of diagnosing a wound incorrectly, if possibilities to perform differential diagnostics are lacking (19, 27).

As a solution, a broader range of differential diagnostic possibilities as regards the origin of the wound would probably help in the first evaluation and in avoiding diagnostic error and delay in the treatment (30-31). One practical tool to tackle these diagnostic challenges could be the use of checklists (32-34). It has been determined in other contexts that there are tools for avoiding fatal errors in differential diagnostics, such as existing guidelines and, to be regarded with a grain of salt, electronic aids in decision making (35-37)

Limitations

The limitations of this study are related to the variety of aetiologies behind chronic wounds. There are no generally agreed-upon diagnostic codes to be used for chronic wounds, and the differentiation potential is enormous. Most often wounds are coded as merely a wound of unspecified aetiology (L97, L98), or they are S-coded, which refers to a traumatic wound. Therefore, it is difficult to define when a diagnosis is correct or not.

Outliers also constituted a limitation of the study, as we could not include them in the data analysis. Some patients in the material had suffered from a wound for several years. Despite this, they were referred to the wound care team when it was established in 2013. In our delay analyses, we tried to avoid this bias by selecting patients whose wounds had appeared less than one year prior to the appointment with the wound care team.

Conclusion

It seems that the diagnostic delay of wound patients occurs within primary care. It is an organisational delay and causes patient harm, as the patients are not receiving a timely and correct diagnosis and treatment. Infectious wounds seem to be easy to detect, but there is a risk of overdiagnosis, leading to an overuse of antibiotics. However, primary care physicians seem to pay little attention to distinguishing arterial insufficiency or diabetic foot ulcers (DFU).

The delay before seeing a primary care physician was not substantial, but the physicians' differential diagnostic approaches did not cover peripheral arterial disease or diabetic foot ulcers. Consequently, the delay before being seen by the wound care team was over one month, which is a long time when treating diabetic foot ulcers, especially those of vascular origin.

Based on our results, we propose that it is possible to arrange an optimal treatment pathway within a primary care setting, where a holistic wound care process is initiated, provided that there is organisational support, knowledge, skills and a multidisciplinary team available. It has been demonstrated that such an approach does not even require any additional resources, but rather a rearrangement of the patient care (16, 38). We also suggest that the specialist care clinics could play a supportive role in the treatment of complex wounds, while the primary care system could take responsibility for the holistic wound care.

Ethics: Not applicable/No human participants included.

Contributorship statement:

Kirsti Ahmajärvi is the responsible guarantor of content and has contributed to the planning, conduct, and reporting of the work described in the article.

Kirsi Isoherranen has contributed to the planning and reporting of the work described in this article.

Maarit Venermo has contributed to the following parts in this study: Design of the study, data analysis and interpretation, revisions to scientific content of the manuscript, review and editing of the final manuscript.

The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Competing interest: All authors have completed the ICMJE uniform disclosure form at Helsinki and declare: Kirsi Isoherranen and Maarit Venermo has no support from any organisation for the submitted work, Kirsti Ahmajärvi has received a working grant from the University of Helsinki, The Finnish Wound Association and The Finnish Association for General Practice. ; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Data sharing statement: Data is not available in any system for data sharing.

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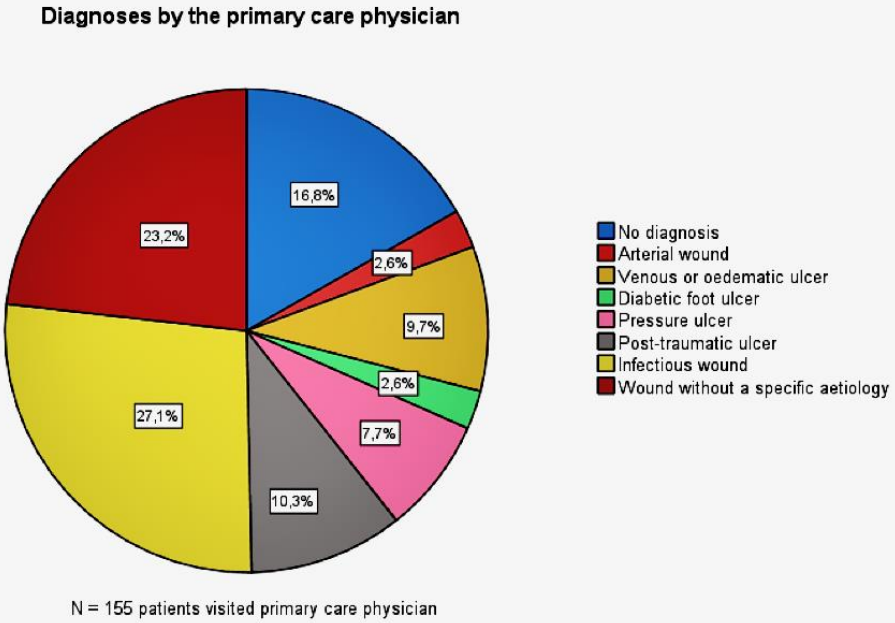
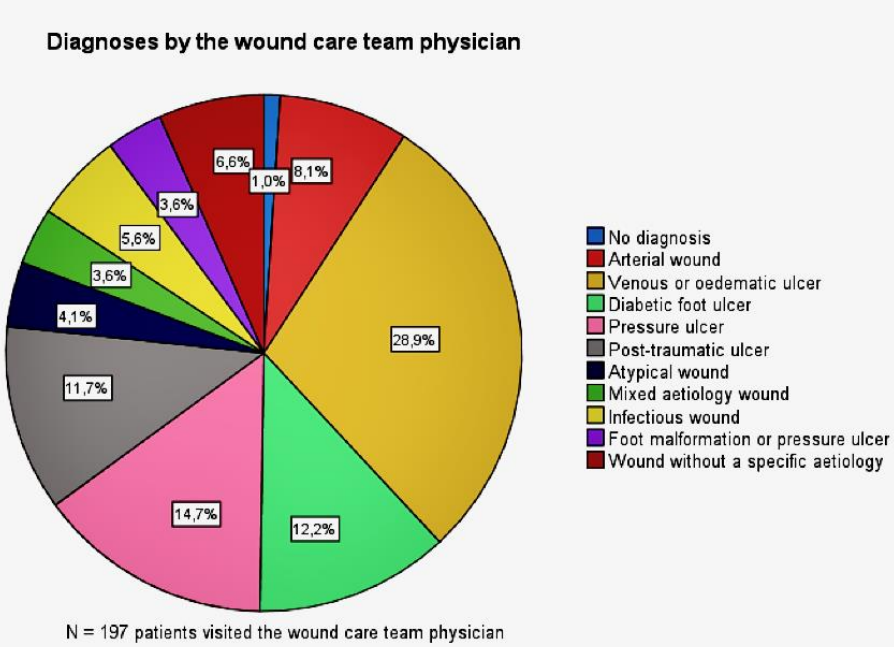
Figure 1





Supplementary Table 1. Diagnostic codes included in the 10 chosen diagnostic categories.

Category	no.	ICD-10 codes
Arterial wound	1	I70.2, L97, E10.4, E11, E11.7, E11.5, E11.4, M10, R60, S91.1, S81.8
Venous or oedematous ulcer	2	S81.8, S81.2, R60, R60.9, L97, I83, I83.0, I83.2, I87.2, I89.0, I88.0, R66+R60+L97
Diabetic ulcer	3	E11 + L97, E11.7+L97, E11.5, M20.2, M20.4, S92.5, E11.4+L97, E11.8+L97+I70.2, E11.7+S91.3, E11.5+L97, E11+G30.1, E10.7+L97, E10.6+M14.2+L97, N08.39*E11.2+L97, E10+L97, E10.6+R02+L07, E11.2+L97, E10.4+L97
Pressure ulcer	4	L89, G58.7 + L97, I69.3+L89+L97
Post-traumatic wound	5	S80, T22, S81, S81.1, T24.4, T24.0, S81.8, S81.0, S81.8, T93.0, S91.0, S51.9, S01.1
Atypical wound	6	C44.75, C44.72, S01.3, D23.2, L90.5, T95.2, L88, K42.9, S31.3, T09.1
Mixed aetiology	7	I70.2+L97+I83, I70.2+R60+L97, T33.5+M86, T33.4+M86, I87.2+I70.2+E11.7+L97
Infectious wound	8	L02.4, L02, L02.3, L02.9, L03, L05.0, A46, L08.8, L08, L08.9, L05, L05.0, L05.9, L00, T79.3, A49.9, M86.6+L89, L30, L72, L72.0, L72.1, K61.0, K60.3, K60
Foot malformation/pressure	9	L97, L89, I70.2 +L97, L97+M10, M05.9+L89
Wound of unspecified aetiology	10	S71.0, S82.3, S91.3, S91.0, S91, S81.3, S81, S81.9, L97, S86.0, M71.1, S41.1, T13.1, L98.4, T93.0, T81.4, T81.3

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	5	A cohort study
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found		
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported		Chronic wounds pose a significant burden to health care, both to the patients and to the system. Diagnostic process begins from primary care, and there should be timely diagnostic processes for patients suffering from a wound
Objectives	3	State specific objectives, including any prespecified hypotheses	5	We analysed delay in the treatment of patients with chronic wounds and analyzed also the diagnostic process among wound patients. Furthermore, we evaluated the impact of a special wound care team within primary care on this process
Methods				
Study design	4	Present key elements of study design early in the paper	6	A cohort was collected
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6	A cohort was collected in April-September 2016, in Helsinki health care centre at first visit to a wound care team and included

			197 consecutive patients. The patient records were analysed both backwards and onwards for data collection. Data collection included onset of the wound until endpoint which was healing. Diagnostic delays were recorded by collecting the dates of first visit in the health services, wound care team and specialist care and by collecting the diagnosis found from the patient record.
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Criteria: Patients suffering for a chronic wound and sent to a wound care team consultation within primary care at their first visit there. Follow-up from patient records as well as gathering the data backwards from the patient records until the onset of the wound. Additionally, demographic data, the number of visits to health care and earlier examinations were collected. The diagnoses set at the first visit, at the wound care team and at the specialist care visit were compared.
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed	

		Case-control study—For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6	For delay article we examined the dates and diagnostic codes of each visit for a physician in the health care system throughout the clinical treatment path. We examined how the ICD-codes differentiated between physicians´ and which diagnostical procedures and tests or treatment was used to determine the correct diagnosis.
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8	Data collected from the patient records.
Bias	9	Describe any efforts to address potential sources of bias	8	Potential bias is the variation of the diagnostic codes, ICD-10, as the diagnostic procedures varied remarkably. We have explained in the article how we decided the date of the correct diagnosis. Also outliers constitute a possible bias. Some had been suffering from a wound for years and/or the wound never healed.
Study size	10	Explain how the study size was arrived at	6	We collected 197 patients: No power estimates have been done.

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6	We removed patients who had wounds over 365 days prior the wound care team visit from the delay analyses, but included them in the descriptive analyses for basic demography.
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9	We were using SPSS for statistical analysis. Descriptives and Frequencies, Explore, Means were used. Two-Independent Samples Test were used.
		(*b*) Describe any methods used to examine subgroups and interactions	9	Two-Independent Samples Test were used, (Mann-Whitney-U test) when comparing the subgroups and differences in delays between them and Pearsons chii-square and ANOVA-tests when comparing subgroups of male and female in background descriptives
		(*c*) Explain how missing data were addressed		Not much missing data. We analysed the groups and removed the outliers from delay analyses.
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy		No loss to follow-up
		(*e*) Describe any sensitivity analyses		
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8	197 patients included in the study 182 patients in the delay analyses

		(b) Give reasons for non-participation at each stage	6	Excluded from the delay analyses patients which had onset of the wound over 365 days prior the wound care team visit.
		(c) Consider use of a flow diagram		
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7,13	Characteristic are found in the table 1–3
		(b) Indicate number of participants with missing data for each variable of interest		Missing data: fP-Gluk n=4, HbA1c n=44, LDL n=28, BMI n=19, ABI primary care n=179, ABI wound care team n=86
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)		Follow-up from the first visit in the wound care team for until wound healing or 365days.
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	18,19	Delays are presented in Median days (IQR;Min-Max;Range) **Patient-related delay** 2(0-14;0-351;351), From onset of the wound to first physician evaluation 8(1-32;0-314;314), From onset of the wound to wound care team(**diagnostic delay**) 57(33-101;2-358;356), From the first contact to wound care team(**organizational delay**) 42(22-80;1-484;483) wound care team to specialist 21(7-52;-58-252;414)
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		
		Cross-sectional study—Report numbers of outcome events or summary measures		

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	18-19	Median patient-related delay was 2 days (IQR 0-14), physicians´ first evaluation 8 days(1-32), wound care team 57days (33-101) Organizational delay from first contact to health services to diagnosis was 42 days(22-80)
		(*b*) Report category boundaries when continuous variables were categorized		
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period		

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	14	21.3% out of 197 were not seen by primary care physician. Of those who met the physician, the diagnosis was recorded in 129 cases. The diagnosis was consistent with the diagnosis of the wound care team was in 59 cases.
Discussion				
Key results	18	Summarise key results with reference to study objectives		Key results are: the delay for correct diagnosis is median 57 days from the onset of the wound, whereas optimate wound diagnosis should occur in 14 days. The delay is organizational (and diagnostical) since the first physician contact is median 8 days from the onset of the wound and there was a minimum patient-related delay.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	23	The same as in Bias- section. Also one limitation might be selection bias, when all patients are sent to a consultation. Additionally, there was not a comparison group (patients with chronic wounds and not possibilities for a wound care team consultation/before the establishment of the team).
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	23	This study describes the diagnostic processes and delays of patients with wounds in Helsinki

				metropolitan area. Our conclusion and suggestion is, that it is beneficial to organize wound care teams in the firstline in the primary care to detect as soon as possible the wounds and to start optimal care for these patients. Avoiding delays and erroneous diagnosis is essential in avoiding patient harm and costs.
Generalisability	21	Discuss the generalisability (external validity) of the study results		This study provides a model for the primary care; how to make wound care safer for the patients with a little effort, team education, re-organization and support from the specialist care. Similar teams could be arranged anywhere in primary care.
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24	Funding is for Kirsti Ahmajärvi , responsible author, from the University of Helsinki to work some months as PhD Student("out-of office"-vacations for studies) Also Grants for a couple of months from non-profital organizations to support the PhD work ("out-of office"-vacations supports) The Finnish Wound Association and The Finnish Association for General Practice

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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A Cohort Study of Diagnostic Delay in the Clinical Pathway of Patients with Chronic Wounds in the Primary Care Setting

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Title page

A Cohort Study of Diagnostic Delay in the Clinical Pathway of Patients with Chronic Wounds in the Primary Care Setting

Authors:

1. Kirsti Ahmajärvi, MD, PhD Student, Specialist in General Practice, Special Competence in Wound Management
2. Kirsi Isoherranen, MD, PhD, Specialist in Dermatology and Allergology, Special Competence in Wound Management
3. Maarit Venermo, MD, PhD, Professor of Vascular Surgery

Address and position of each author:

University of Helsinki, P.O. Box 4, 00014 University of Helsinki

1. K Ahmajärvi, MD, PhD Student, Specialist in General Practice, University of Helsinki, Doctoral Programme in Populational Health and Department of General Practice and Primary Health Care, University of Helsinki and Helsinki University Hospital, Helsinki, Finland. Helsinki University Hospital, P.O. Box 250, 00029 Helsinki

2. K Isoherranen, MD, PhD, Specialist of Dermatology and Allergology, Skin and Allergy Hospital, Meilahdentie 2, 00029 HUS, Finland.

3. M Venermo, MD, PhD, Vascular Surgeon, Professor of Vascular Surgery, Head of the Department, University of Helsinki and Helsinki University Hospital, Haartmaninkatu 4, 00290 Helsinki, Finland

Affiliations:

1. K Ahmajärvi, MD, PhD Student, University of Helsinki, Doctoral Programme in Populational Health and Department of General Practice and Primary Health Care, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

2. K Isoherranen, MD, PhD, Department of Dermatology and allergology, University of Helsinki and Inflammation Center, Helsinki University Hospital, Helsinki, Finland

3. M Venermo, MD, PhD, Vascular Surgeon, Professor of Vascular Surgery, Head of the Department, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

Corresponding Author: Kirsti Ahmajärvi

Correspondence to: kirsti.ahmajarvi@helsinki.fi

ORCiD: Kirsti Ahmajärvi: https://orchid.org/0000-0001-9106-5915

ORCiD: Kirsi Isoherranen: https://orcid.org/0000-0002-0253-2567

ORCiD: Maarit Venermo: https://orcid.org/0000-0001-8814-0988

Kirsti Ahmajärvi is the responsible guarantor of content and has contributed to the designing the study, conducting, collecting and analyzing the data, and reporting of the work described in the article.

Kirsi Isoherranen has contributed to the following parts of the study: design of the study, reporting and review and editing of the final manuscript.

Maarit Venermo has contributed to the following parts in this study: Design of the study, data analysis and interpretation, revisions to scientific content of the manuscript, review and editing of the final manuscript.

The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Ethics: This is a retrospective registry-based study. Data were anonymised before the authors assessed them for the purpose of the study. As no data was collected directly from the patients, according to Finnish regulations no ethical approvement was needed. The study and data collection was approved in the IRB of Abdominal center, Helsinki University Hospital and in the IRB of City of Helsinki.

Keywords: chronic wound, leg ulcer, foot ulcer, wound management, wound aetiology, primary care, diagnostic process, diagnostic delay, clinical pathway

Words 4632

Abstract

Objectives: Exact wound diagnosis is essential for successful wound management and a holistic care of the patient suffering from a wound. Wound management has been traditionally seen as a nursing area, but this can lead to considerable delays in wound diagnostics. A diagnostic delay has been recognised as an element of diagnostic error, which, in turn, affects patient safety. The aim of this cohort study was to examine diagnostic delays of chronic wound within primary care.

Setting: A specialised diagnostic unit, a wound care team, was established in the primary health care with the objective of reducing diagnostic and treatment delays in primary care.

Participants: The data consists of 197 consecutive patients attending their first appointment with the wound care team in 2016. The collected data included basic demographics, information about the clinical pathway, including doctor's appointments in primary and specialised care, as well as the ICD-10 diagnostic codes.

Primary and secondary outcome measures: The diagnostic delays were calculated in days and divided into three groups: 1) patient-related delay, 2) diagnostic delay and 3) organisational delay.

Results: The median duration of a patient-related delay was two days (IQR 0-14), whereas a physician's first evaluation was performed at a median of 8 (1–32) days from wound appearance and the correct diagnosis by the wound care team was established in a median of 57 (33-100) days. The organisational delay from first contact to diagnosis was a median of 41 (22–80) days. Only one in three patients had a diagnostic delay of less than 4 weeks.

Conclusions: According to this study, the diagnostic delay occurs within primary care, as an organisational delay from first contact to correct diagnosis It is possible to arrange an optimal pathway of care in which a holistic wound care process starts within primary care.

Bullet points of the study:

Strengths and limitations of this study:

Strengths of the study include a unique data which contain primary care patients suffering from chronic wounds.

Strengths include also systematic and detailed data review and collection.

Limitations include the possibility of interpretation bias.

Limitations include also the possibility of error in defining the moment of “the right diagnosis”.

There is not input for Patient and Public Involvement in the study design, which could be seen as a limitation.

A COHORT STUDY OF DIAGNOSTIC DELAY IN THE CLINICAL PATHWAY OF PATIENTS WITH CHRONIC WOUNDS IN THE PRIMARY CARE SETTING

Introduction

Chronic wounds pose a significant burden to health care, constituting roughly 2%–6% of all health care costs (1-3). According to a recent study in the UK, the annual prevalence of wounds increased by 71% between 2012/2013 and 2017/2018 and patient management costs increased by 48% in real terms (4). In addition to costs, chronic wounds cause substantial suffering at the individual level, leading to an impaired quality of life, social isolation and mental health problems (5-7). Wound management can be successful only when the wound is correctly diagnosed and treated accordingly (8,9). Wound care has been traditionally viewed as measures related to the assessment of the wound bed, which can obscure the importance of the holistic care of the patient (10).

In many European countries, wound patients are first seen in primary care by general practitioners (GPs) or nurses (11). This poses a significant challenge to primary care: wound patients should receive a timely evaluation by a qualified health care professional who can make the correct diagnosis, plan holistic treatment and make the necessary referrals (12). This process should aim to avoid diagnostic error, which has been recognised by the World Health Organization (WHO) as a global challenge to patient safety (13). Diagnostic error includes an incorrect or delayed diagnosis, which leads to patient harm or to inappropriate or delayed treatment. The diagnostic errors mainly occur within primary care or at the emergency department, where physicians lack the appropriate tools and sufficient time to make accurate decisions (14, 15).

In 2013, a special wound care team was established in the primary health care system of the Helsinki area. The wound care team consists of a wound care nurse and a general practitioner specialised in wound care. This team has the possibility to consult a podiatrist and/or vascular surgeon. Patients are referred to a wound care team consultation from all primary care units: health centres, home care units and nursing homes. The instructions for the primary care personnel were to react early and refer patients suffering from a non-healing wound within (2–)4 weeks of wound appearance in order to have the wound appropriately diagnosed. The main focus of the wound care team was to discover the correct diagnosis as early as possible and, thereafter, to initiate proper treatment accordingly.

The purpose of this study was to evaluate the delay in the diagnostic process in the clinical pathway of wound patients who were referred for a consultation by the wound care team during 2016. The delays were divided into system-related and patient-related delays.

Material and methods

This prospective cohort study analysed the characteristics and medical history of 197 consecutive patients who visited the wound care team in primary health care during 2016. The information was collected at the first wound care team appointment.

Data were collected from electronic patient records. The collected data consisted of patients' background factors (sex, age, comorbidities, medication, previous wounds, state of mobility and living standards, need of home care, smoking, blood sugar levels and lipids), as well as the date of wound appearance, the date of the patient's first contact with a primary care unit and physician's appointment, the date of consulting the wound care team, and the date of admission to a specialist care unit if needed. In order to analyse the diagnostic process, additional information was collected on signs of infection and bacterial swab results, on whether the ankle brachial index (ABI) was measured, or pulse palpation occurred, or whether neuropathy was detected with a monofilament test. Observations of oedema and any blood test analyses regarding the wound were also recorded. Furthermore, information was gathered from radiological examinations, if performed, as well as any further investigations within specialist care, such as toe pressure and angiography results. The treatment plan was evaluated and compared to the diagnostic methods and the ICD-10 code. (Supplementary Table 1)

Delays were calculated at different points of the care pathway, starting from wound appearance. The different types of delays included: 1) patient-related delay (time from wound appearance to the patient's first contact with health care providers), 2) diagnostic delay (time from the onset of the wound to the first physician's appointment where the initial diagnosis was made), and 3) organisational delays within primary care in arriving at the correct diagnosis and treatment (from the first contact with the primary health care unit to the wound care team consultation). Some patients needed a referral to a specialist consultation, his delay was also considered.

Diagnostic codes were collected as ICD-10 codes and we compared to the diagnoses made by the primary care physician, by the wound care team physician and by the specialist. As the number of different diagnostic codes was high, we categorised the diagnoses into ten groups (Table 1, Figures 1a and 1b). In the grouping process, we also included, in addition to the diagnostic code, information on how the wound had appeared and which diagnostic tools had been used to arrive at the specific conclusion and treatment plan.

Table 1. Categorisation and diagnostic variation in the clinical pathway of a patient with a wound.

Diagnostic categories	Primary care physician (n = 155)	Wound care team physician (n = 197)	Specialist care physician (n = 111)
No diagnosis*	26	2	1
Arterial wound	4	16	26
Venous or oedematous ulcer	15	57	17
Diabetic foot ulcer	4	24	15
Pressure ulcer	12	29	9
Post-traumatic wound	16	23	3
Atypical wound	0	8	7
Mixed-aetiology ulcer	0	7	3
Infectious wound	42	11	10
Foot malformation or pressure ulcer	0	7	1
Wound of unspecified aetiology	36	13	19

*The category was defined as 'no diagnosis' when a patient had been seen by a physician but there was no ICD-10-coded diagnosis in the patient records.

In order to avoid bias caused by outliers, 16 patients whose wound had persisted for over 365 days prior to the wound team consultation were excluded from the delay analysis.

Patient and public Involvement

No patient or public involvement has been occurred in planning, managing, designing or carrying out this research.

Results

A total of 197 patients were included in the study. The mean age was 71 years, and 106 (53,5%) patients were female. The basic demographics and risk factors of the patients are reported in Tables 2-3.

Table 2. Basic demographics.

	Female(n)	%	Male (n)	%	Total (n)	%
Sex	106	53.8	91	46.2	197	100
Age (y)						
Mean	78	39.6	69	97.2	71	36.0
Median	80	40.6	73	37.1	41	20.8
Mobility (n)						
walking	38	19.3	56	28.4	94	47.7
walking with assistance device	33	16.8	20	10.2	53	26.9
walking with device only indoors	16	8.1	5	2.5	21	10.7
wheelchair	11	5.6	8	4.1	19	9.6
bedridden	8	4.1	2	1.0	10	5.1
Residence (n)						
home	57	28.9	73	37.1	130	66.0
home with home care	30	15.2	12	6.1	42	21.3
assisted living facility	14	7.1	5	2.5	19	9.6
24/7 care nursing home	5	2.5	1	0.5	6	3.0

Table 3 Description of the sample (n = 197, % of total) in individuals; comorbidities and risk factors.

Comorbidities	Female (n)	%	Male (n)	%	Total (n)	%	p-value*
Hypertension	60	30.5	50	25.4	110	55.8	
Heart failure	25	12.7	11	5.6	36	18.3	p = 0.044
Ischaemic heart disease	13	6.6	10	5.1	23	11.7	
Atrial fibrillation	37	18.8	24	12.2	61	31.0	
Respiratory condition	27	13.7	11	5.6	38	19.3	
Cancer	14	7.1	14	7.1	28	14.2	
Mental Health condition	9	4.6	9	4.6	18	9.1	
Dementia/memory disorder	25	12.7	9	4.6	34	17.3	p = 0.013
Diabetes	30	15.2	47	23.9	77	39.1	p < 0.001
Peripheral arterial disease	16	8.1	24	12.2	40	20.3	p = 0.042
Kidney malfunction	12	6.1	15	7.6	27	13.7	
Rheumatoid arthritis	15	7.6	6	3.0	21	10.7	p = 0.091
Liver malfunction	0	0.0	6	3.0	6	3.0	p = 0.007
Spinal stenosis	5	2.5	3	1.5	8	4.1	
Gout	3	1.5	8	4.1	11	5.6	p = 0.064
Haematological condition	5	2.5	6	3.0	11	5.6	
Chronic pain disorder	2	1.0	0	0.0	2	1.0	
Urinary condition	4	2.0	10	5.1	14	7.1	p = 0.045
Cerebrovascular disorder	15	7.6	13	6.6	28	14.2	
Dermatological disease	3	1.5	2	1.0	5	2.5	
Musculoskeletal disorder	21	10.7	7	3.6	28	14.2	p = 0.018
No comorbidities	3	1.5	4	2.0	7	3.6	

Risk factors	Female (n)	%	Male (n)	%	Total (n)	%	p-value*
Previous wounds	46	23.4	50	25.4	96	48.7	
Previous DVT	9	4.6	1	0.5	10	5.1	p = 0.020
venous insufficiency	9	4.6	7	3.6	16	8.1	
chronic oedema	3	1.5	2	1.0	5	2.5	
chronic cellulitis	10	5.1	5	2.5	15	7.6	
previous amputation	4	2.0	1	0.5	5	2.5	
Smoking (n)	13	6.6	28	14.2	41	20.8	p = 0.001
Drug abuse	2	1.0	5	2.5	7	3.6	p = 0.010
Alcohol abuse	3	1.5	11	5.6	14	7.1	
Overweight (BMI 24–30)	59	29.9	62	31.5	121	61.4	
Obesity (BMI over 30)	26	13.2	29	14.7	55	27.9	
High cholesterol (diagnosis)	22	11.2	23	11.7	45	22.8	
LDL over 3.0	23	11.7	19	9.6	42	21.3	
Joint malformation	8	4.1	3	1.5	11	5.6	p = 0.010
Neuropathy (diagnostic coded)	8	4.1	18	9.1	26	13.2	p < 0.001
Neuropathy (monofilament test posit.)	32	16.2	54	27.4	86	43.7	
MRSA	2	1.0	6	3.0	8	4.1	p = 0.048

hemiplegia	2	1.0	2	1.0	4	2.0	
HbA1c(n=153)							
Mean (SD)	43 (12.9)		49 (16.8)		46(15.1)		p = 0.018~
Median (IQR)	40		43		41(37 - 52)		
BMI(n=178)							
Mean(SD)	27.4 (8.2)		29.0 (6.2)		28 (7.4)		
Median	26		28		26 (23 - 32)		
fP-Kol-LDL(n=169)							
Mean(SD)	2.5 (0.83)		2.4 (0.86)		2.5 (0.84)		
Median	2.4		2.3		2.4 (1.8-3.0)		
fP-Gluk(n=173)							
Mean(SD)	6.0 (1.8)		7.3 (3.4)		6.6 (2.7)		p = 0.002~
Median	5.8		6.7		5.9 (5.3-6.9)		

*Pearsons chi-squared, difference between female and male patients

~One-way ANOVA test

The majority of the patients were living at home (n = 172; 86.9%) either without any support (n = 130) or with home care (n = 42). The patients' living status is presented in Table 2. Almost half of the patients had had wounds earlier (48.7%). As regards comorbidities, 39.1% had diabetes, 11.7% ischemic heart disease, 17.3% memory disorders and 9.1% a mental health condition. Only 3.6% had no comorbidities. Overweight (61.4%), obesity (27.9%) and neuropathy (43.4%) were relatively common. Venous insufficiency or a previous deep venous thrombosis had been diagnosed in only 13.2%. As can be seen in Tables 3 and 4, the patients had several co-morbidities and heterogenous medications. Almost half of the patients used analgesics (44.7% NSAIDs or paracetamol and 15.2% opioids), whereas different psychopharmaceuticals were used by 11.7%–17.8% of the patients.

Table 4. Description of the sample (n = 197) in individuals; medication.

Medication	Female (n)	%	Male (n)	%	Total (n)	%	chi-square
Cardiac and vessel medicine							
Anticoagulant	41	20.8	26	13.2	67	34.0	p = 0.164
Antithrombotic	29	14,7	28	14.2	57	28.9	
b-blocker	57	28.9	41	20.8	98	49.7	
Diuretic	45	22.8	32	16.2	77	39.1	
Ca-blocker	27	13.7	31	15.7	58	29.4	
ACE-blocker	38	19.3	47	23.9	85	43.1	p = 0.018
Statin	40	20.3	35	17.8	75	38.1	
Diabetes medicine							
Oral diabetes medicine	16	8.1	21	10.7	37	18.8	p = 134
Insulin	12	6.1	30	15.2	42	21.3	p < 0.001
Psychopharmaceuticals							
Dementia medicine	16	8.1	6	3.0	22	11.2	p = 0.066
Antidepressant	14	7.1	11	5.6	25	12.7	
Benzodiazepine	13	6.6	10	5.1	23	11.7	
Sleeping pills	23	11.7	12	6.1	35	17.8	p = 0.135
Analgesia(mild)	57	28.9	31	15.7	88	44.7	p = 0.008
Opiates	18	9.1	12	6.1	30	15.2	
Immune system medicine							
Cancer medicine	2	1.0	3	1.5	5	2.5	
Immunosuppressive	11	5.6	4	2.0	15	7.6	p = 0.124
Cortisone per oral	12	6.1	4	2.0	16	8.1	p = 0.083
Cortisone cream	4	2.0	0	0.0	4	2.0	p = 0.064
Supplements							
Thyroxin	16	8.1	3	1.5	19	9.6	p = 0.006
Ca-supplement	46	23.4	16	8.1	62	31.5	p < 0.001
Folic acid	7	3.6	3	1.5	10	5.1	
B12-supplement	11	5.6	12	6.1	23	11.7	
Vitamin D suppl.	44	22.3	22	11.2	66	33.5	p = 0.013
Nutrition suppl.	6	3.0	2	1.0	8	4.1	
Mg suppl.	7	3.6	4	2.0	11	5.6	
K suppl.	11	5.6	9	4.6	20	10.2	
Other							
Inhaler/nebulizer	26	13.2	16	8.1	42	21.3	
Proton pump inhibitor	39	19.8	20	10.2	59	29.9	p = 0.030
Urine medicine	8	4.1	12	6.1	20	10.2	
Skin cream	19	9.6	10	5.1	20	10.2	p = 0.190

Diagnostics

Forty-two (21.3%) patients were not seen by a primary care physician before they visited the wound care team, meaning that the diagnostic process was not even started before this visit. Of the 155 patients who had been seen by a physician prior to the wound care team, 129 (83.2%) had a recorded diagnosis code (ICD-10), while 26 (16.8%) patients remained undiagnosed. Thus, 34.5% of the patients (n = 68) received their first diagnosis by the wound care team.

Out of the patients who were seen by a primary care physician, 85 (58.8%) had no delay (median 0 days), meaning that the patients visited an emergency room and were seen by a physician immediately. The diagnoses for these patients mainly comprised infectious wounds (n = 30, 35.3%) and wounds with no specific cause (n = 21, 24.7%), while a diagnostic code was not recorded for 10.6% (n = 9). Hence, 15 patients had traumatic wounds and saw the physician at an acute appointment.

Of those patients who saw a primary care physician (n = 155), 36.2% (n = 56) had clinical signs of infection according to the patient records. However, as many as 94 (60.6%) patients were treated with antibiotics, and 82 (52.9%) had a bacterial swab taken.

Of the 129 patients who had a diagnosis before the first appointment with the wound care team, the same diagnosis was made by the team and the primary care physician in 59 (45.7%) of the cases. The concordant diagnoses most often entailed pressure ulcers, infectious ulcers, as well as venous and post-traumatic ulcers. Specialist care was received by 111 patients. The same diagnosis (ICD-10) was made by all three points in the clinical pathway in only 24 (12.2%) cases, and the majority of these comprised infectious ulcers, followed by a venous aetiology and wounds without a specific diagnosis. (Table 5)

Table 5. Differentiation of the diagnoses when they remained unchanged or were revised over the clinical pathway.

	Diagnoses that remained unchanged		Diagnoses that were revised		
Categorised diagnostic groups	within primary care	throughout the entire clinical pathway	by wound care team and specialist care	Primary care physician's diagnosis	Wound care team physician's diagnosis
Arterial wound	0	0	16	4	7
Venous or oedematous ulcer	13	5	17	2	24
Diabetic foot ulcer	2	1	13	2	11
Pressure ulcer	11	3	9	1	8
Post-traumatic wound	15	3	3	0	2
Atypical wound	0	0	7	0	4
Mixed-aetiology wound	0	0	2	0	3
Infectious wound	10	8	9	32	1
Foot malformation or pressure ulcer	0	0	1	0	5
Wound of unspecified aetiology	8	4	6	27	3

Of the patients who visited a specialist, the same diagnosis was made by the wound care team physician and the specialist in 75.5% of the cases (Table 5 and 6). The concordant diagnoses most often comprised diabetic foot ulcers (20.5%), arterial ulcers (19.3%) and venous or oedematous ulcers (15.7%). In the remaining 24.6% (n = 27) of the patients, the diagnosis made by the wound care team was revised in specialist care, mostly comprising arterial ulcers (40.7%) that were usually referred for further investigations with a suspicion of an arterial wound. The ulcers that turned out to be arterial wounds were diagnosed by the wound care team as diabetic foot ulcers (14.8%), wounds of mixed aetiology (18.5%), foot malformations (14.8%) and oedematous ulcers (37.0%).

Post-traumatic wounds were categorised into one category. In the primary care setting, there were 16 post-traumatic ulcers, 15 of which were assessed in the emergency room (ER).

Table 6. Diagnostic differentiation through the treatment pathway.

	The same diagnosis~ throughout entire treatment pathway	The same diagnosis within primary care~~~	The same diagnosis by wound care team and specialist
1 = the same	24	60	83
0 = different	47	67	27
total	71	127[#]	110
% of diagnosed*^ patients	21,8	47,2	75,5
% of 197 (whole sample)	12,2	30,5	42,1

~ treatment pathway: primary care physician, wound care team (physician) and specialist care.
~~~primary care physician and wound care team (physician)
*155 patients visited a doctor in primary care before the appointment with the wound care team, but only 129 patients were diagnosed.
^110 patients were diagnosed in specialist care.
[#]2 patients were undiagnosed in the wound care team. They were of those of the 129 diagnosed in the primary care
~~~

Delays

The median time from wound appearance to the first health care contact was 2 days (IQR 0–14 days, range 0–351 days) and from wound appearance to the first evaluation by a physician 8 days (IQR 1–32 days, range 0–314 days). The majority of the patients had their first health care contact at the emergency department where a physician also examined the patient, or at the district nurse's office at a health centre with the possibility of an immediate physician's consultation. The median time from the onset of the wound to the first wound care team appointment was 57 days (IQR 33–100 days, range 2–358 days). The median time between the first health care contact and the wound care team appointment was 41 days (IQR 22–80 days: range 1–484 days). Only one in three patients (n = 61) had an organisational delay of less than 4 weeks between the first contact with health services and the appointment with the wound care team.

Half of the patients (n = 113, 57.4%) were referred to a secondary health care unit to be seen by a specialist, most often by a vascular surgeon (n = 67), followed by a plastic surgeon (n = 43) and a dermatologist (n = 13). Twenty-one (18.6%) patients were referred to two or more specialists. The median delay from the first appointment with the wound care team to the appointment with the secondary health care specialist was 21 days (IQR 8–55, min–max -58–235; range 293 days).

The median time from the appearance of the wound to the final diagnosis was 57 days (IQR 33–101; min–max 2–358; range 356 days).

The delays in different the subgroups are presented in Table 7.

Table 7. Delays in different subgroups. Figures are presented as medians (IQR; Min–Max; Range)

Delays are calculated and analysed with the inclusion criterion 'wound appearance within 365 days prior to wound care team appointment'.

	n	Wound appearance - first contact to health care	Wound appearance to first physician evaluation	Wound appearance to wound care team	Delay from first contact to wound care team (organizational delay within primary care)	Delay Wound care team to specialist care	Mann-Whitney-U
All patients	182	2 (0–14;0–351;351)	8(1–32;0–314;314)	57(33–101;2–358;356)	42(22–80;1–484;483)	21(7–52;-58–252;414)	
Male	81	3 (0–24;0–351;351)	9(1–37;0–314;314)	69(37–111;2–358;356)*	44(23–85;2–484;482)	23(3–48;-58–235;293)	*p = 0.058
Female	101	1 (0–8;0–295;295)	8(1–24;0–295;295)	54(30–96;2–306;304)*	41(22–76;1–264;263)	20(8–58;0–176;176)	
Age under 65 y (1)	46	6 (1–27;0–298;298)*	9(3–30;0–142;142)	62(36–100;11–320;309)	37(22-76;6–382;376)	28(14–48;1–182;181)	*1 vs 2; p = 0.005
Age 65–80 y (2)	62	0 (0–14;0–258;258)*	10(0–38;0–314;314)	61(41–106;10–337;327)	49(25–88;4–264;260)	16(2–50;0–235;235)	*1 vs 3; p = 0.003
Age over 80 y (3)	74	1 (0–8;0–351;351)*	7(1–32;0–295;295)	53,5(30–98;2–358;356)	40(22–78;1–484;483)	16(6–56;-58–167;225)	
DM+	72	1 (0–15;0–142;142)	10(1–37;0–142;142)	59(36–102;2–324;322)	45(26–75;2–245;243)	14(3–48;0–235;235)	no statistical
DM-	110	2 (0–13;0–351;351)	7(1–32;0–314;314)	56(31–101;4–358;354)	40(22–84;1–482;483)	26(8–56;-58–167;225)	difference
Living at home	160	2 (0–15;0–351;351)	9(1–33;0-314;314)	57(33–102;2–358;356)	42(22–83;1–382;381)	20(5–48;0–235;235)*	*p = 0.010
Living in institution	22	1 (0–8;0–295;295)	3(0–14;0–295;295)	55(34–86;7–306;299)	43(24–72;7–484;477)	56(16–143;-58–176;234)*	
Walking; outdoors	134	3 (0–15;0–351;351)*	8(1–27;0–246;246)	56(33-97;4–358;354)	40(22–76;1–382;381)	22(6–56;-58–235;293)	*p = 0.047
Not-walking; staying indoors	48	0 (0–5;0–298;298)	9(1–55;0–314;314)	71(33–108;2–337;335)	54(24–94;2–484;482)	16(7–46;0–182;182)	
Delay before wound care team under 28 days	61	6 (0–20;0–351;351)*	7(3–24;0–295;295)	26(19–41;2–358;356)*	18(12–22;1–28;27)	22(4–42;0–167;167)	*p < 0.001
Delay before wound care team over 28 days	121	0 (0–8;0–258;258)	9(0–34;0–314;314)	73(51–112;29–337;308)	70(42–101;29–484;455)	20(7–55;-58–235;293)	
Unchanged diagnosis (PC–WT–spec.)	20	3 (2–12;0–246;246)	7(3–19;0–246;246)	51(32–80;5–267;262)	35(20–74;2–186;184)	23(8–45;0–89;89)	
Different diagnosis	43	1 (0–17;0–258;258)	8(0–42;0–314;314)	71(37–111;4–337;333)	57(30–89;1–245;244)	18(7–98;0–235;235)	
The same DG within primary care	55	2 (0–7;0–246;246)	3(1–18;0–246;246)	52(31–78;5–267;262)*	40(20–71;2–186;184)	33(9–56;0–176;176)	*p=0.042
Different DG	61	1 (0–24;0–258;258)	17(1–56;0–314;314)	73(37–126;4–337;333)	53(31–98;1–245;244)	15(7–64;0–235;235)	

Discussion

It is well-known that an early diagnosis of the underlying cause of a chronic wound is essential for wound healing and for avoiding amputations (8, 16, 17). However, there are only a few studies describing the importance of wound diagnosis and the deleterious effects of diagnostic delays (18-20). In the current study, we investigated the diagnostic processes and delays in wound care in the Helsinki area. The patients' first contact with health care services after wound appearance was prompt, the median delay being only 2 days. In stark contrast, it took 57 days from the appearance of the wound before the patient was seen by the wound care team for the first time. In our material, only 31.0% of the patients visited the wound care team within 4 weeks of the first health care appointment. This caused a significant delay in reaching the correct diagnosis of the wound. We also discovered that only 65.5% of all patients had a recorded wound diagnosis before the first wound care team appointment and that this diagnosis matched the final diagnosis in approximately 50% of the cases. Accordingly, in European countries, the delay in diagnosing diabetic foot ulcers (DFU) was over 3 weeks in 21%–34% of the patients. The shortest average time from event to diagnosis was 10 days in the UK, 14 days in Spain and France, and 20 days in Germany. (12)

In Finland, wound patients are evaluated and treated mainly during primary care appointments, including home care and nursing homes (21). In the mentioned European countries, the health care professionals who participate in the diagnostic process vary considerably. In the UK, only 6% of GPs completely agreed that the care and management of DFUs is the GP's responsibility, and 22% did not diagnose DFUs. Instead, in 27% of the cases, district nurses made the diagnosis. In the UK, the approach seems more often to be multidisciplinary, as 49% of the GPs referred patients to a podiatrist if needed. In all four countries, GPs were able to refer DFU patients to specialised multidisciplinary clinics. (22)

In the UK, DFUs were diagnosed by a GP in only 45% of the cases, and most of the wounds were diagnosed by a district nurse or practice nurse (12).

The optimal treatment pathways for wound patients include patient surveillance and an early detection of wound healing problems. Errors in the pathway may lead to delays and, consequently, even fatal errors, such as amputations, in some patients. (17)

We took a closer look at the ICD-10 codes assessed by the primary care physicians, wound care team physician and specialists and found that they differed from each other significantly. This highlights the complexity of wound diagnostics. Surprisingly, only 12.2% of the patients had the same diagnosis throughout the whole pathway of care, and these mostly comprised infectious wounds. Based on our data, we assume that there was a significant overdiagnosis of infections in primary care, since an infectious wound was diagnosed in 32.6% of the cases and antibiotics were prescribed for 63.2% of the patients in the primary care setting. Similar results have been obtained in Sweden, where the use of a national wound register diminished the use of antibiotics (23). Evidence of difficulties in the diagnostics of wound infections is also found in a study of GPs recognising and treating wound infections – according to the results, GPs mostly desired further knowledge about when to start or stop treatment (81%–82%), about topical antimicrobials (80%–68%) and about when to prescribe antibiotics (82%–95%) (24).

Another diagnostic challenge was the diagnosis of an ischaemic wound and diabetic foot ulcer in primary care. Only four diabetic and arterial ulcers were diagnosed in primary care. In contrast, the wound care team diagnosed a DFU in 54 patients, and 26 patients were referred to a specialist when an ischaemic wound was suspected. This problem is also detected in a multi-centre study performed in four European countries. The researchers found that, even though GPs described neuropathy and peripheral arterial disease as cofactors in the DFU development, they investigated DFUs with additional tests in only half of the cases; this entailed monofilament tests in 21%–43% and, more often, pulse palpation or the measurement of the ankle brachial index in 78%–90% of the cases, but diabetic foot infection (DFI) was tested in only 7%–20% of the investigated cases. (11)

Our main finding was that there was an organisational delay in reaching a timely diagnosis. The time between wound appearance and the first contact with a physician was adequate, the median being 8 days, and two-thirds (58.8%, n = 85) of the patients had their first evaluation at the first contact with health services. This means that a physician's examination was mostly available at the emergency room or as a rapid consultation during a nurse's appointment at the health centre. However, our study shows that, among these patients, the initial physician's evaluation very seldom leads to a correct diagnosis and treatment.

Regarding wound patients, emergency room assessment should include the three most important and acute aetiologies, such as infection, ischaemia and diabetes (25), but otherwise the emergency room might not be the optimal setting for diagnosing wounds.

Post-traumatic ulcers could be a subgroup of oedematous leg ulcers due to the same management approach, namely compression therapy, which should be assessed immediately after vascular/arterial causes have been ruled out. Hence, according to the present data, oedematous and post-traumatic ulcers accounted for 40.6% of all the ulcers and were treated with compression.

We found that the wound diagnostic process was good enough in the wound care team, as the diagnosis did not change for 75.5% of the patients who were referred by the team to specialist care. In the remaining 24.5%, in whom the diagnosis made by a specialist differed from the diagnosis made by the wound care team, the final diagnosis was confirmed using diagnostic tools that were not available in the health centre. In these cases, however, the wound care team often had a default diagnosis to base the referral on, and specialist care then responded to this idea, most often leading to the correct treatment. Indeed, the referral was very useful for these patients.

On the other hand, there were ordinary delays in receiving a specialist evaluation, as the median delay was 21 days, where the largest differences were between the subgroups of patients living in institutions and those living at home. This might be explained by the advance care planning among nursing home residents. However, previous studies propose delays of less than two weeks in diagnosing arterial ulcers and DFUs to avoid leg losses (17). As a response to the challenge of timely referral to correct department for treatment there are globally several multidisciplinary wound clinics to have only one place to send a patient for a consultation (26,27,28).

Previous studies suggest that diagnostic errors are often preceded by common symptoms, followed by common diagnoses (29, 30). Studies have shown that the most frequent error is "premature closure", meaning 'the tendency to stop considering other possibilities after reaching a diagnosis' (31, 32). In the UK, diagnosis- and assessment-related incidents were the highest causes of patient harm (29). As a conclusion, the ability to utilise differential diagnostic methods is key when diagnosing wound aetiologies. There is always a danger of diagnosing a wound incorrectly, if possibilities to perform differential diagnostics are lacking (19, 30).

As a solution, a broader range of differential diagnostic possibilities as regards the origin of the wound would probably help in the first evaluation and in avoiding diagnostic error and delay in the treatment (33-34). Our study shows that the problem for wound management lies in the primary care; i.e. wounds that should be referred to multidisciplinary care are not recognized. The solution is continuous education of primary care physicians and nurses focusing on basic differential diagnostics of chronic wounds instead of wound management *per se*. Education is needed also to bring up the awareness of the triage –remembering that also an acute wound may turn into a chronic wound which needs quick response and treatment. One practical tool to tackle these diagnostic challenges could be the use of checklists (35-37) and digitalized wound diagnostic tools (38, submitted for publication). It has been determined in other contexts that there are tools for avoiding fatal errors in differential diagnostics, such as existing guidelines and, to be regarded with a grain of salt, electronic aids in decision making (39-41).

Limitations

The limitations of this study are related to the variety of aetiologies behind chronic wounds. There are no generally agreed-upon diagnostic codes to be used for chronic wounds, and the differentiation potential is enormous. Most often wounds are coded as merely a wound of unspecified aetiology (L97, L98), or they are S-coded, which refers to a traumatic wound. Therefore, it is difficult to define when a diagnosis is correct or not.

Outliers also constituted a limitation of the study, as we could not include them in the data analysis. Some patients in the material had suffered from a wound for several years. Despite this, they were referred to the wound care team when it was established in 2013. In our delay analyses, we tried to avoid this bias by selecting patients whose wounds had appeared less than one year prior to the appointment with the wound care team.

Conclusion

It seems that the diagnostic delay of wound patients occurs within primary care. It is an organisational delay and causes patient harm, as the patients are not receiving a timely and correct diagnosis and treatment. Infectious wounds seem to be easy to detect, but there is a risk of overdiagnosis, leading to an overuse of antibiotics. However, primary care physicians seem to pay little attention to distinguishing arterial insufficiency or diabetic foot ulcers (DFU).

The delay before seeing a primary care physician was not substantial, but the physicians' differential diagnostic approaches did not cover peripheral arterial disease or diabetic foot ulcers. Consequently, the delay before being seen by the wound care team was over one month, which is a long time when treating diabetic foot ulcers, especially those of vascular origin.

Based on our results, we propose that it is possible to arrange an optimal treatment pathway within a primary care setting, where a holistic wound care process is initiated, provided that there is organisational support, knowledge, skills and a multidisciplinary team available. It has been demonstrated that such an approach does not even require any additional resources, but rather a rearrangement of the patient care (16, 42). We also suggest that the specialist care clinics could play a supportive role in the treatment of complex wounds, while the primary care system could take responsibility for the holistic wound care.

Ethics: Not applicable/No human participants included. This is a retrospective registry-based study. Data were anonymised before the authors assessed them for the purpose of the study. Due to the nature of the study ethical approval was not required for the study. Study was approved in the IRB of Abdominal center, Helsinki University Hospital and in the IRB of City of Helsinki.

Contributorship statement:

Kirsti Ahmajärvi is the responsible guarantor of content and has contributed to the designing the study, conducting, collecting and analyzing the data, and reporting of the work described in the article.

Kirsi Isoherranen has contributed to the following parts of the study: design of the study, reporting and review and editing of the final manuscript.

Maarit Venermo has contributed to the following parts in this study: Design of the study, data analysis and interpretation, revisions to scientific content of the manuscript, review and editing of the final manuscript.

The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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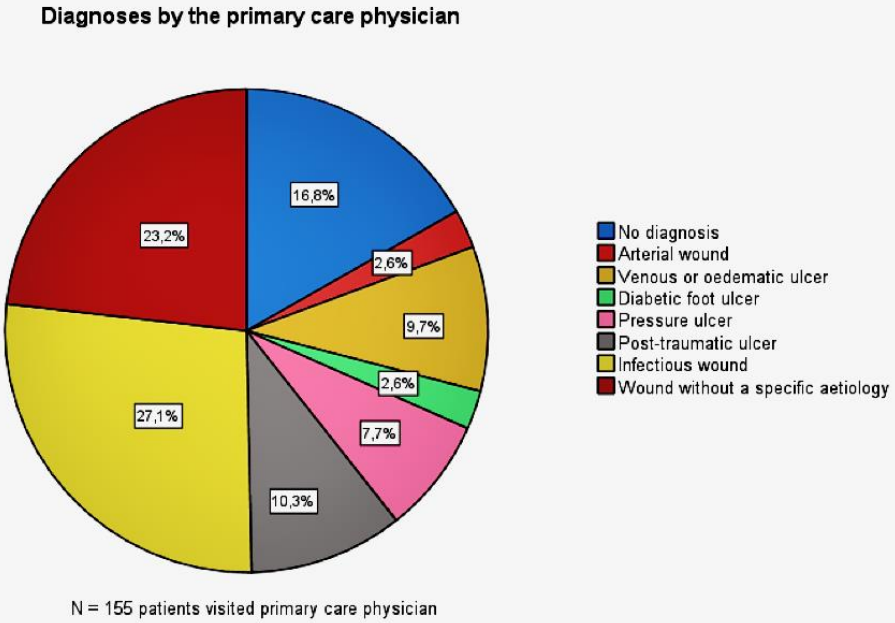
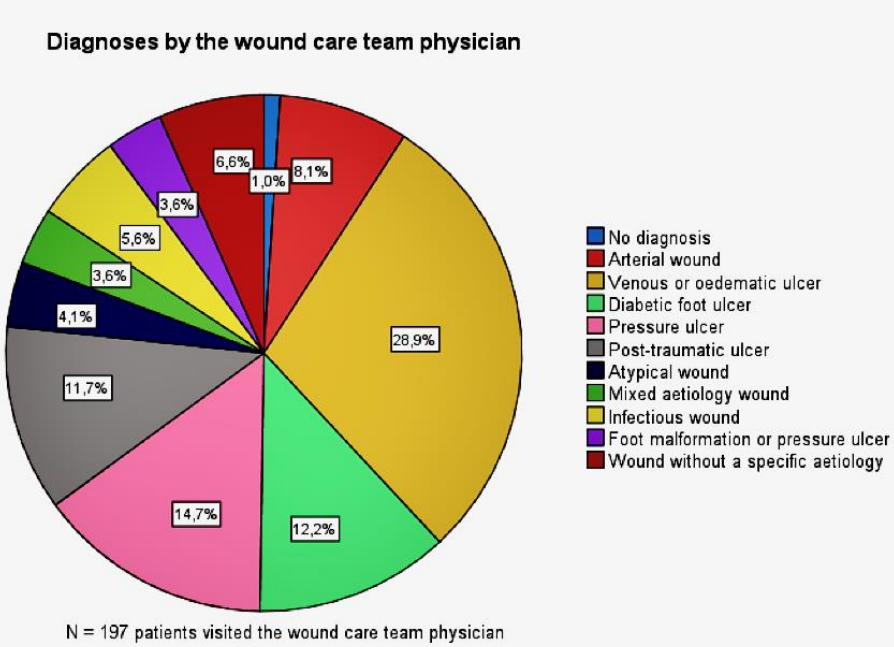
Figure 1





Supplementary Table 1. Diagnostic codes included in the 10 chosen diagnostic categories.

Category	no.	ICD-10 codes
Arterial wound	1	I70.2, L97, E10.4, E11, E11.7, E11.5, E11.4, M10, R60, S91.1, S81.8
Venous or oedematous ulcer	2	S81.8, S81.2, R60, R60.9, L97, I83, I83.0, I83.2, I87.2, I89.0, I88.0, R66+R60+L97
Diabetic ulcer	3	E11 + L97, E11.7+L97, E11.5, M20.2, M20.4, S92.5, E11.4+L97, E11.8+L97+I70.2, E11.7+S91.3, E11.5+L97, E11+G30.1, E10.7+L97, E10.6+M14.2+L97, N08.39*E11.2+L97, E10+L97, E10.6+R02+L07, E11.2+L97, E10.4+L97
Pressure ulcer	4	L89, G58.7 + L97, I69.3+L89+L97
Post-traumatic wound	5	S80, T22, S81, S81.1, T24.4, T24.0, S81.8, S81.0, S81.8, T93.0, S91.0, S51.9, S01.1
Atypical wound	6	C44.75, C44.72, S01.3, D23.2, L90.5, T95.2, L88, K42.9, S31.3, T09.1
Mixed aetiology	7	I70.2+L97+I83, I70.2+R60+L97, T33.5+M86, T33.4+M86, I87.2+I70.2+E11.7+L97
Infectious wound	8	L02.4, L02, L02.3, L02.9, L03, L05.0, A46, L08.8, L08, L08.9, L05, L05.0, L05.9, L00, T79.3, A49.9, M86.6+L89, L30, L72, L72.0, L72.1, K61.0, K60.3, K60
Foot malformation/pressure	9	L97, L89, I70.2 +L97, L97+M10, M05.9+L89
Wound of unspecified aetiology	10	S71.0, S82.3, S91.3, S91.0, S91, S81.3, S81, S81.9, L97, S86.0, M71.1, S41.1, T13.1, L98.4, T93.0, T81.4, T81.3

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	5	A cohort study
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found		
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported		Chronic wounds pose a significant burden to health care, both to the patients and to the system. Diagnostic process begins from primary care, and there should be timely diagnostic processes for patients suffering from a wound
Objectives	3	State specific objectives, including any prespecified hypotheses	5	We analysed delay in the treatment of patients with chronic wounds and analyzed also the diagnostic process among wound patients. Furthermore, we evaluated the impact of a special wound care team within primary care on this process
Methods				
Study design	4	Present key elements of study design early in the paper	6	A cohort was collected
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6	A cohort was collected in April-September 2016, in Helsinki health care centre at first visit to a wound care team and included

			197 consecutive patients. The patient records were analysed both backwards and onwards for data collection. Data collection included onset of the wound until endpoint which was healing. Diagnostic delays were recorded by collecting the dates of first visit in the health services, wound care team and specialist care and by collecting the diagnosis found from the patient record.
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Criteria: Patients suffering for a chronic wound and sent to a wound care team consultation within primary care at their first visit there. Follow-up from patient records as well as gathering the data backwards from the patient records until the onset of the wound. Additionally, demographic data, the number of visits to health care and earlier examinations were collected. The diagnoses set at the first visit, at the wound care team and at the specialist care visit were compared.
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed	

		Case-control study—For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6	For delay article we examined the dates and diagnostic codes of each visit for a physician in the health care system throughout the clinical treatment path. We examined how the ICD-codes differentiated between physicians´ and which diagnostical procedures and tests or treatment was used to determine the correct diagnosis.
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8	Data collected from the patient records.
Bias	9	Describe any efforts to address potential sources of bias	8	Potential bias is the variation of the diagnostic codes, ICD-10, as the diagnostic procedures varied remarkably. We have explained in the article how we decided the date of the correct diagnosis. Also outliers constitute a possible bias. Some had been suffering from a wound for years and/or the wound never healed.
Study size	10	Explain how the study size was arrived at	6	We collected 197 patients: No power estimates have been done.

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Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6	We removed patients who had wounds over 365 days prior the wound care team visit from the delay analyses, but included them in the descriptive analyses for basic demography.
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9	We were using SPSS for statistical analysis. Descriptives and Frequencies, Explore, Means were used. Two-Independent Samples Test were used.
		(*b*) Describe any methods used to examine subgroups and interactions	9	Two-Independent Samples Test were used, (Mann-Whitney-U test) when comparing the subgroups and differences in delays between them and Pearsons chii-square and ANOVA-tests when comparing subgroups of male and female in background descriptives
		(*c*) Explain how missing data were addressed		Not much missing data. We analysed the groups and removed the outliers from delay analyses.
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy		No loss to follow-up
		(*e*) Describe any sensitivity analyses		
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8	197 patients included in the study 182 patients in the delay analyses

		(b) Give reasons for non-participation at each stage	6	Excluded from the delay analyses patients which had onset of the wound over 365 days prior the wound care team visit.
		(c) Consider use of a flow diagram		
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7,13	Characteristic are found in the table 1–3
		(b) Indicate number of participants with missing data for each variable of interest		Missing data: fP-Gluk n=4, HbA1c n=44, LDL n=28, BMI n=19, ABI primary care n=179, ABI wound care team n=86
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)		Follow-up from the first visit in the wound care team for until wound healing or 365days.
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	18,19	Delays are presented in Median days (IQR;Min-Max;Range) **Patient-related delay** 2(0-14;0-351;351), From onset of the wound to first physician evaluation 8(1-32;0-314;314), From onset of the wound to wound care team(**diagnostic delay**) 57(33-101;2-358;356), From the first contact to wound care team(**organizational delay**) 42(22-80;1-484;483) wound care team to specialist 21(7-52;-58-252;414)
		Case-control study—Report numbers in each exposure category, or summary measures of exposure		
		Cross-sectional study—Report numbers of outcome events or summary measures		

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	18-19	Median patient-related delay was 2 days (IQR 0-14), physicians´ first evaluation 8 days(1-32), wound care team 57days (33-101) Organizational delay from first contact to health services to diagnosis was 42 days(22-80)
		(*b*) Report category boundaries when continuous variables were categorized		
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period		

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Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	14	21.3% out of 197 were not seen by primary care physician. Of those who met the physician, the diagnosis was recorded in 129 cases. The diagnosis was consistent with the diagnosis of the wound care team was in 59 cases.
Discussion				
Key results	18	Summarise key results with reference to study objectives	23	Key results are: the delay for correct diagnosis is median 57 days from the onset of the wound, whereas optimate wound diagnosis should occur in 14 days. The delay is organizational (and diagnostical) since the first physician contact is median 8 days from the onset of the wound and there was a minimum patient-related delay.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	23	The same as in Bias- section. Also one limitation might be selection bias, when all patients are sent to a consultation. Additionally, there was not a comparison group (patients with chronic wounds and not possibilities for a wound care team consultation/before the establishment of the team).
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	23	This study describes the diagnostic processes and delays of patients with wounds in Helsinki

				metropolitan area. Our conclusion and suggestion is, that it is beneficial to organize wound care teams in the firstline in the primary care to detect as soon as possible the wounds and to start optimal care for these patients. Avoiding delays and erroneous diagnosis is essential in avoiding patient harm and costs.
Generalisability	21	Discuss the generalisability (external validity) of the study results		This study provides a model for the primary care; how to make wound care safer for the patients with a little effort, team education, re-organization and support from the specialist care. Similar teams could be arranged anywhere in primary care.
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24	Funding is for Kirsti Ahmajärvi , responsible author, from the University of Helsinki to work some months as PhD Student("out-of office"-vacations for studies) Also Grants for a couple of months from non-profital organizations to support the PhD work ("out-of office"-vacations supports) The Finnish Wound Association and The Finnish Association for General Practice

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.