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RESEARCH ARTICLE

Implementation of a quality improvement initiative in Belgian diabetic foot clinics: feasibility and initial results

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Abstract

Background This article aims to describe the implementation and initial results of an audit–feedback quality improvement initiative in Belgian diabetic foot clinics.

Methods Using self-developed software and questionnaires, diabetic foot clinics collected data in 2005, 2008 and 2011, covering characteristics, history and ulcer severity, management and outcome of the first 52 patients presenting with a Wagner grade ≥2 diabetic foot ulcer or acute neuropathic osteoarthropathy that year. Quality improvement was encouraged by meetings and by anonymous benchmarking of diabetic foot clinics.

Results The first audit–feedback cycle was a pilot study. Subsequent audits, with a modified methodology, had increasing rates of participation and data completeness. Over 85% of diabetic foot clinics participated and 3372 unique patients were sampled between 2005 and 2011 (3312 with a diabetic foot ulcer and 111 with acute neuropathic osteoarthropathy). Median age was 70 years, median diabetes duration was 14 years and 64% were men. Of all diabetic foot ulcers, 51% were plantar and 29% were both ischaemic and deeply infected. Ulcer healing rate at 6 months significantly increased from 49% to 54% between 2008 and 2011. Management of diabetic foot ulcers varied between diabetic foot clinics: 88% of plantar mid-foot ulcers were off-loaded (P10–P90: 64–100%), and 42% of ischaemic limbs were revascularized (P10–P90: 22–69%) in 2011.

Conclusions A unique, nationwide quality improvement initiative was established among diabetic foot clinics, covering ulcer healing, lower limb amputation and many other aspects of diabetic foot care. Data completeness increased, thanks in part to questionnaire revision. Benchmarking remains challenging, given the many possible indicators and limited sample size. The optimized questionnaire allows future quality of care monitoring in diabetic foot clinics.

Keywords diabetic foot; audit–feedback; quality improvement

Introduction

Diabetic foot ulceration (DFU) is a common late-stage complication of diabetes, with up to 25% of individuals with diabetes experiencing a DFU in their lifetime and with high recurrence rates [1,2]. It has a large impact both on

quality of life [3] and on resource utilization, the latter mainly driven by long hospital stays [4,5].

Although performing a foot examination in diabetic patients is an accepted quality of care indicator assessing the efforts of health care practitioners in preventing new DFUs [6], there are few established indicators for monitoring quality of DFU care in specialized diabetic foot clinics (DFCs). The Eurodiale study reported that actual care of DFUs did not correspond well to the management recommendations set forth in international guidelines and that their application showed high variability between DFCs [7]. The authors of the Eurodiale study suggested that the existing guidelines were too general and that the HCP's personal beliefs too often guided treatment, resulting in an underuse of recommended treatment strategies.

Monitoring of performance and providing feedback to health care practitioners (audit–feedback), including benchmarking of DFCs, is one strategy to improve quality of care [8]. In 2001, a quality improvement initiative based on audit–feedback cycles, covering both processes and outcomes of care, was established in over 100 Belgian hospital-based diabetes centres. This initiative improved adherence to diabetes care guidelines, mostly with regard to processes of care [9]. In 2005, the existing audit–feedback initiative was extended to Belgian multidisciplinary DFCs that complied with a predefined structure of care. The aim was not only to evaluate the impact of multidisciplinary care in these DFCs but also to identify challenges and shortcomings in the implementation of DFU management recommendations with the aim of improving quality of care. Here, we describe the implementation of this quality improvement initiative, its optimization over the years and the initial results, in terms of patient and ulcer characteristics, management and outcomes.

Materials and methods

Study population

Since 2005, Belgian multidisciplinary DFCs, assembling expertise from diabetologists or internists with experience in the treatment of diabetes, vascular and orthopaedic surgeons and podiatrists and wound care specialists, can apply for recognition by the health authorities. Recognized DFCs agree to provide true multidisciplinary care during consultation hours to patients suffering from diabetic foot problems. Other disciplines (dermatologists, pharmacists etc.) are involved in some DFCs, but this is not necessary for recognition.

To qualify for continued recognition, DFCs need to treat at least 52 diabetic patients with a new index 'foot problem' each year: either a DFU of grade 2 or more, according to the Wagner wound classification system [10], or an acute neuropathic osteoarthropathy (acute Charcot foot). The audit–feedback initiative is limited to these 52 patients. If a DFC treats more patients meeting these criteria, only the first 52 patients are considered for audit–feedback, leading to a more limited representativeness for the larger DFCs. Some DFCs choose to register more patients satisfying the aforementioned criteria to improve the representativeness of the feedback reports sent to them (see in the following text).

In order to investigate the representativeness of the obtained sample, DFCs were invited during the most recent audit (2011) to provide ulcer grading data and the presence of an acute Charcot foot for all their patients. This group of patients will be referred to in the text as the '2011 clinic population' and will be compared with the sample of 52 patients, referred to as the '2011 audit sample'.

Audit

There have been three audits (2005, 2008 and 2011) using different study designs: entirely retrospective in 2005 and 2008 and mixed retrospective/prospective in 2011 (audit started 6 months after start of patient eligibility). All audits used a standardized electronic questionnaire with separate sheets for entry of baseline and follow-up data. This questionnaire was developed during meetings with an expert committee composed of diabetologists, orthopaedic and vascular surgeons, podiatrists, epidemiologists and experts in quality audits and quality improvement. After each cycle, the methodology was reviewed and altered if deemed necessary. At baseline, the DFCs abstracted the following data from the patients' medical records: age, sex, postal code, diabetes type and duration, smoking status, relevant medical history, referral pattern, type of foot problem (DFU and/or Charcot foot) and ulcer location and severity, according to both the Wagner [10] and PEDIS [11] classification systems.

During follow-up (1 year in 2005 and 6 months in 2008 and 2011), management of the foot problem (off-loading, vascular diagnostics, revascularization, orthopaedic surgery and podiatric interventions) and ulcer and patient outcomes (ulcer healing, major amputation or death; relapse or new ulcers) were recorded by the DFCs. Ulcer healing was defined as complete epithelialization with or without minor amputation (amputation below the ankle).

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After completion of follow-up, DFCs transferred the data to the Scientific Institute of Public Health, an independent semi-governmental organization, for data quality checks, analysis and generation of feedback reports. Participation is mandatory, possibly resulting in doubtful quality and validity of the data. To alleviate these concerns, health authorities do not have access to the raw data, and they only see pooled results. The DFCs have to keep a list of the sampled patients for a possible on-site audit. The expert committee adopts a bottom-up approach and does not include representatives of the authorities.

Feedback of data to DFCs

The DFCs received individualized feedback reports, containing the following analyses: (1) indications of data completeness, (2) comparison of the DFC's patient and ulcer characteristics with those of the median DFC to allow identification of possible case-mix differences and (3) scores and caterpillar plots (Figure 1(A) and (C)) on selected quality of care indicators to allow benchmarking. During each cycle, pooled results were also presented and discussed during meetings open to all recognized DFCs and their team members. At the end of each cycle, a global report based on the pooled results was published (see http://www.wiv-isp.be/epidemio/), containing recommendations for future audit–feedback cycles and for improving quality of diabetic foot care in Belgian DFCs.

Funnel plot analysis

Two process-of-care quality indicators were chosen for a funnel plot analysis [12]: (1) the rate of off-loading of plantar mid-foot ulcers (off-loading of ulcer, foot and/or

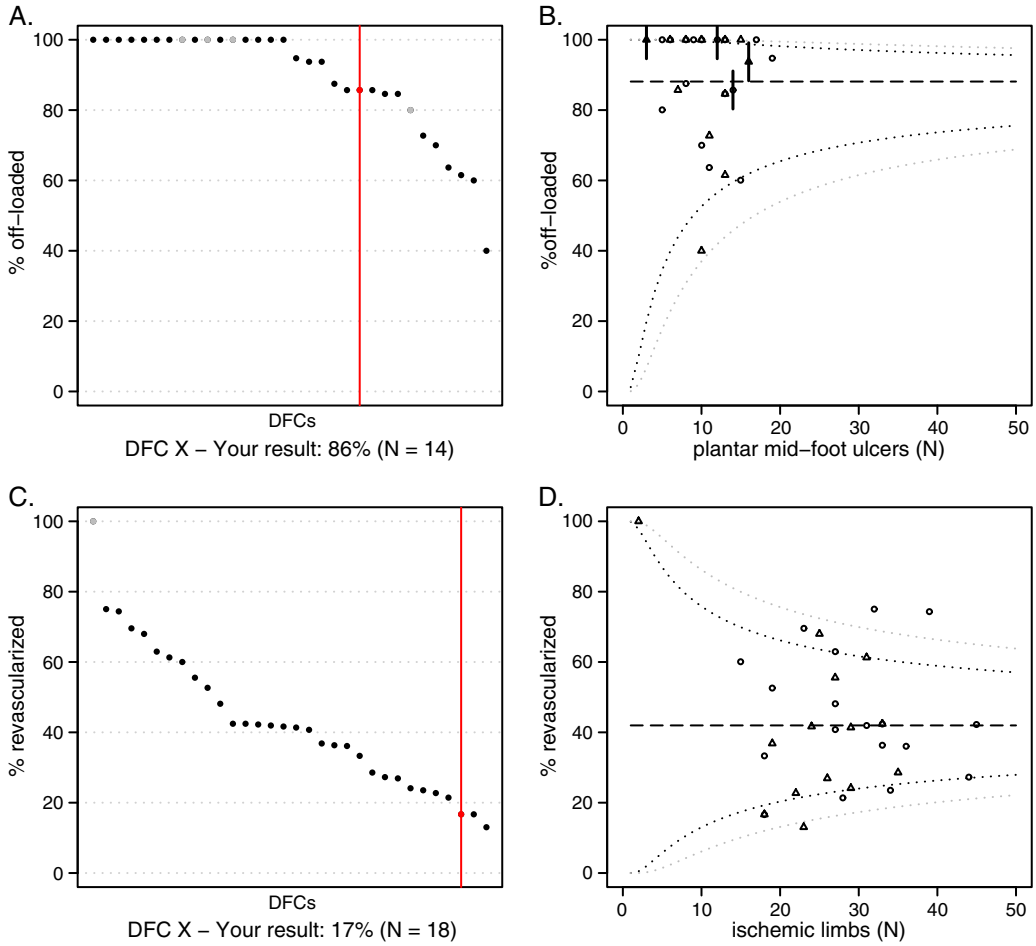

Figure 1. (A) and (C) Caterpillar plots for the indicator 'Percentage of plantar mid-foot ulcers off-loaded' (top) and 'Percentage of ischaemic limbs revascularized' (bottom), as provided in the 2011 feedback report to diabetic foot clinic (DFC) 'X' (in red). (B) and (D) Funnel plots based on the data from panels A and C, additionally showing whether the score applies to a previously participating diabetic foot clinic (circles) or a first-time participant (triangles). The horizontal dashed line shows the overall indicator score, and the funnel-shaped dotted lines show the 2 (in black) and 3 (in grey) standard deviations control limits. In case of two overlapping data points, a vertical marker is shown

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lower leg by any means except by crutches, wheelchair or bed rest) and (2) the rate of revascularization (endovascular or surgical) of ischaemic limbs (PEDIS-perfusion grade of 2 or more). Funnel plots show the individual rate per DFC as a function of the number of plantar mid-foot ulcers or ischaemic limbs (Figure 1 (B) and (D)). The sample size, which is plotted on the *x*-axis, is an interpretable measure of the precision with which the rates were measured. Superimposed are 'control limits' that typically mark the threshold of 2 and 3 standard deviations (SD) around the overall rate, roughly coinciding with the 95.0% and 99.9% prediction limits, respectively, (Figure 1(B) and (D)). DFCs lying beyond the 2 SD limit were considered 'outliers'.

Statistical analysis

For the description of patients and foot problems, data from the three audits were pooled. Unique patients were identified, and only the episode pertaining to the first foot problem was kept for analysis. Statistical testing for differences in medians and proportions was carried out using the Kruskal–Wallis and χ^2-test, respectively. All analyses were performed in STATA (version 10.1, StataCorp, College Station, TX, USA). Statistical significance was defined as $p < 0.05$. No adjustment was made for multiple testing.

Results

Implementation of audit–feedback and methodological changes

The number of recognized DFCs increased from 22 in 2005–2008 to 36 in 2009–2011. They were located in all regions of Belgium, although almost exclusively in urban areas and more often in the densely populated northern region. Audit participation rates were high, and over 1000 patients were sampled each audit (Table 1). Some DFCs failed to provide valid data for the required minimum of 52 patients (Table 1); although barring some exceptions, they usually missed the target by only one or two patients. Fewer than 50 patients were sampled by no DFCs in 2005, one DFC in 2008 (5%) and five DFCs in 2011 (14%).

After each cycle, the audit methodology was reviewed by an expert committee. The first audit was conceived of as a pilot study. One major methodological change was the shortening of the follow-up period from 1 year to 6 months after the first cycle of audit–feedback, making process and outcome data from 2005 incomparable with those of later audits.

The questionnaires have been relatively stable in terms of characteristics and outcomes of patients and ulcers. By contrast, in an effort to more accurately reflect the care delivered, parameters pertaining to patient referral and management of the foot problem have undergone significant changes after the 2005 audit, both in terms of preciseness (definitions) and exhaustiveness (e.g.

Table 1. Participation rates and data completeness of reported patient characteristics across the three audits

	2005	2008	2011	p[a]
Participating DFCs, *n/N* (%)	19/22 (86.4)	19/21 (90.5)	32/36 (88.9)	—
Sampled patients, *N* (range of sampled patients per diabetic foot clinic)	1048 (50–75)	1006 (2–70)	1600 (23–60)	—
Sex[b]	100.0	100.0	100.0	—
Birth year[b]	100.0	100.0	100.0	—
Diabetes duration	77.2	75.0	78.6	0.106
Diabetes type	98.6	98.8	98.1	0.362
Smoking status	71.1	89.9	94.4	<0.001
Cardiovascular history[c]	95.9	96.0	99.6	<0.001
History of renal insufficiency or end-stage renal disease[d]	96.3	96.3	98.6	<0.001
History of lower limb revascularization or angioplasty	96.5	95.1	99.1	<0.001
History of diabetic foot ulcer	93.7	96.2	99.1	<0.001
History of minor amputation[e]	N.D.	95.7	99.3	<0.001
History of major amputation[e]	N.D.	94.5	97.7	<0.001

N.D., not determined.
Table shows percentage of patients for whom each data element was reported.
[a]*p*-value for χ^2-test.
[b]These parameters were obligatory.
[c]Defined as history of myocardial infarction, coronary artery bypass grafting, percutaneous coronary intervention, stroke or transient ischaemic attack.
[d]Defined as either (1) serum creatinine >1.5 mg/dL or Modification of Diet in Renal Disease (MDRD) eGFR <50 mL/min/1.73 m^2 (in 2005 and 2008, only the first criterion was used) or (2) end-stage renal disease (defined as renal transplantation or peritoneal or hemodialysis).
[e]Minor amputation was defined as amputation below the ankle. Any amputation above that level was a major amputation. Not determined for patients sampled in 2005.

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addition of questions on vascular diagnostics and podiatric interventions in 2008).

Data completeness

Tables 1 and 2 show that data completeness, with regard to patient and ulcer characteristics, significantly increased across the audits, except for reporting of known diabetes duration, diabetes type and ulcer location. In 2011, 14 DFCs participated for the first time. Data completeness for these first-time participants was not significantly lower than for the previously participating DFCs, except for a small difference in the reporting of ulcer location (98.2% for first-time participating DFCs *vs* 99.8% for previously participating DFCs, $p < 0.01$).

Description of sampled patients and foot problems

Between 2005 and 2011, 3372 unique patients were sampled, 250 patients (7.4%) were sampled in two out of three audits and 21 patients (0.6%) were sampled in all three audits.

Table 3 shows the characteristics of the unique patients. Patient characteristics were comparable for the three audits, except for sex (68.0% of men in 2011 *vs* 61.7% and 62.0% in 2005 and 2008, respectively, $p < 0.01$) and history of DFUs (45.7% in 2005 *vs* 58.7% and 59.5% in 2008 and 2011, respectively, $p < 0.001$).

Table 4 shows the ulcer characteristics of 3312 unique patients with a DFU, of whom 51 patients (1.5%) had a concomitant acute Charcot foot. Severity of DFUs was graded more favourably across the audits (2005, 2008 and 2011), with regard to surface area (≥3 cm^2 in 89.7%, 84.3% and 66.9%, respectively, $p < 0.001$), perfusion [(sub)critical ischaemia in 63.8%, 62.1% and 57.2%, respectively, $p < 0.01$] and infection (deep or systemic infection in 53.2%, 41.7% and 41.0%, respectively, $p < 0.001$). This was paralleled by evolutions in DFU location (plantar location in 48.0%, 54.2% and 51.1%, respectively, $p < 0.05$) and treatment delay (≥3 months in 7.6%, 10.4% and 13.7%, respectively, $p < 0.001$).

Of all unique patients, 111 presented with an acute Charcot foot the first time they were sampled.

Table 3. Characteristics of all unique sampled patients (2005–2011), at the time of their first sampling

Sampled patients, *N*	3372
Male : female ratio	1.815 : 1
Age, years	70 (60–78)
Diabetes duration, years (*N* = 2597)	14 (7–22)
Diabetes type, % T1/T2/other (*N* = 3317)	9.6/89.1/1.3
Smoking, % never/quit/current (*N* = 2891)	50.5/30.3/19.2
Cardiovascular history[a] (*N* = 3283)	37.8
Renal insufficiency or end-stage renal disease[b] (*N* = 3275)	31.7
History of lower limb revascularization or angioplasty (*N* = 3273)	29.3
History of diabetic foot ulcer (*N* = 3258)	55.2
History of minor amputation[c] (*N* = 2281)	22.5
History of major amputation[c] (*N* = 2246)	3.7

Data are presented as median (interquartile range) or as percentage.
[a]Defined as history of myocardial infarction, coronary artery bypass grafting, percutaneous coronary intervention, stroke or transient ischaemic attack.
[b]Defined as either (1) serum creatinine >1.5 mg/dL or MDRD eGFR <50 mL/min/1.73 m^2 (in 2005 and 2008, only the first criterion was used) or (2) end-stage renal disease (defined as renal transplantation or peritoneal or hemodialysis).
[c]Minor amputation was defined as amputation below the ankle. Any amputation above that level was a major amputation.

Representativeness of the 'audit sample'

The audit–feedback initiative was limited to the first 52 patients that presented that year to the DFC with a new DFU of Wagner grade 2 or more and/or an acute Charcot

Table 2. Data completeness of reported ulcer characteristics across the three audits

	2005	2008	2011	P[a]
Sampled diabetic foot ulcers, *N*	1010	992	1584	—
Ulcer location	98.8	98.5	99.1	0.340
Wagner grade	99.5	99.4	100.0	0.012
Lower limb perfusion (PEDIS-perfusion)	93.8	97.7	98.2	<0.001
Ulcer surface area[b] (PEDIS-extent)	75.3	83.0	96.6	<0.001
Ulcer depth (PEDIS-depth)	93.8	98.9	98.9	<0.001
Ulcer infection (PEDIS-infection)	94.5	97.8	99.1	<0.001
Foot sensation (PEDIS-sensation)	89.9	95.4	98.2	<0.001
Treatment delay[c]	60.8	80.7	90.1	<0.001

Table shows percentage of ulcers for which each data element was reported.
[a]*p*-value for χ^2-test.
[b]Surface area was collected as a continuous variable in 2005 and 2008 and was categorized during data analysis.
[c]Treatment delay was defined as time elapsed between onset of diabetic foot ulcers and first presentation in the diabetic foot clinic. Treatment delay was collected as a continuous variable in 2008 and 2011 and was categorized during data analysis.

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Table 4. Location and severity of sampled diabetic foot ulcers of all unique patients (2005–2011)

Sampled DFUs, *N*	3312
Location: plantar (*N* = 3272)	50.9
Location: not limited to toes (*N* = 3272)	48.7
Surface area[a] ≥3 cm^2 (*N* = 2870)	77.3
Depth: probing to bone (*N* = 3223)	30.7
Wagner grade ≥3 (*N* = 3302)	47.8
Loss of protective sensation (*N* = 3141)	84.8
(Sub)critical limb ischaemia (*N* = 3205)	60.5
Deep or systemic infection (*N* = 3225)	44.8
Ischaemic and deeply infected DFUs[b] (*N* = 3219)	28.7
Ischaemic and deeply infected DFUs[b], not limited to toes (*N* = 3249)	12.6
Treatment delay[c], % <1/1–2/≥3 months (*N* = 2598)	62.0/26.6/11.4

DFUs, diabetic foot ulcers.
Data are presented as median (interquartile range) or as percentage.
[a]Surface area was collected as a continuous variable in 2005 and 2008 and was categorized during data analysis.
[b]Combination of (sub)critical ischaemia with a deeply infected DFU or systemic infection.
[c]Treatment delay was defined as time elapsed between onset of DFU and first presentation in the DFC. Treatment delay was collected as a continuous variable in 2008 and 2011 and was categorized during data analysis.

foot. In order to investigate the representativeness of the obtained 'audit sample' with regard to the total clinic population, DFCs were invited during the 2011 audit to provide limited data on ulcer grading and/or the presence of an acute Charcot foot for all their patients. These data with regard to total clinic population were provided by 23 out of 32 participating DFCs in 2011 (72.1%).

In total, 2491 patients were recorded over a period of 12 months (range: 69–239 per DFC). The proportion of patients in the audit sample of 52 patients ranged from 21.3% (for the largest DFC) to 87.0% (for the smallest DFC).

On the basis of the ulcer severity data (*N* = 2461), 708 DFUs (28.8%) were of Wagner grade 1, meaning that >70% of DFUs seen in daily practice were deep. The remaining DFUs of Wagner grade 2 or higher in the clinic population were compared with the DFUs in the audit sample (always Wagner grade 2 or higher), with regard to ulcer severity. Table 5 shows that, with regard to ulcer depth and infection, the observed severity distribution in the 2011 audit sample significantly differed from the expected distribution on the basis of the data of the 2011 clinic population. Superficial ulcers and non-infected ulcers were significantly underrepresented in the audit sample, whereas deeply infected ulcers were significantly overrepresented.

Of all patient data sets, 2461 (98.8%) pertained to a DFU, with or without a concomitant acute Charcot foot, and 76 (3.1%) pertained to an acute Charcot foot, with or without a concomitant DFU. Thus, 46 foot problems (1.8%) pertained to an acute Charcot foot with concomitant DFU. The corresponding proportions in the audit sample were 99.1%, 2.7% and 1.8%, revealing no significant differences with regard to the clinic population.

Table 5. Distribution of ulcer severity according to the PEDIS classification among all patients during the 2011 audit period and among sampled patients, limited to a subset of 23 diabetic foot clinics

	2011 clinic population, *n* (%)	2011 audit sample, *n* (%)	*p*[a]
Perfusion, known	1651 (100.0)	1172 (100.0)	
No PAD	666 (40.3)	499 (42.6)	0.129
Subcritical ischaemia	723 (43.8)	518 (44.2)	
Critical ischaemia	262 (15.9)	155 (13.2)	
Extent, known (cm^2)	1652 (100.0)	1162 (100.0)	
<1	548 (33.2)	399 (34.3)	0.102
1–2	693 (41.9)	514 (44.2)	
≥3	411 (24.9)	249 (21.4)	
Depth, known	1651 (100.0)	1183 (100.0)	
Superficial	194 (11.8)	99 (8.4)	0.010
Deep	906 (54.9)	691 (58.4)	
Probing to bone	551 (33.4)	393 (33.2)	
Infection, known	1648 (100.0)	1184 (100.0)	
No infection	557 (33.8)	300 (25.3)	<0.001
Superficial	502 (30.5)	373 (31.5)	
Deep	497 (30.2)	438 (37.0)	
Systemic	92 (5.6)	73 (6.2)	
Sensation, known	1643 (100.0)	1174 (100.0)	
No LOPS	242 (14.7)	178 (15.2)	0.751
LOPS	1401 (85.3)	996 (84.8)	

LOPS, loss of protective sensation; PAD, peripheral artery disease.
[a]*p*-value for χ^2-test.

Patient and ulcer outcomes

Table 6 shows the outcomes of patients with DFUs at 6 months of follow-up. Because of the longer follow-up period in 2005, only the 2008 and 2011 data will be

Table 6. Patient and ulcer outcomes at a maximum follow-up of 6 months

	Audit period		
	2008	2011	
		Previously (2008) participating DFCs	First-time participating DFCs
Patients/ulcers, *N*	816	861	635
Ulcer healing, %	48.7	53.7*	51.5
Healed after minor amputation, %	9.3	13.0*	8.7**
Major amputation, %	3.8	3.7	4.6
Died before healing, %	3.8	4.5	3.1
Died after major amputation, %	0.7	0.7	0.3
Persisting diabetic foot ulcer, %	44.5	38.8*	41.1

Patients were followed up until ulcer healing, major amputation or death, whichever occurred first.
*$p < 0.05$ *vs* 2008.
**$p < 0.05$ *vs* 2011 rate of previously participating diabetic foot clinics.

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considered. Among the 17 DFCs that participated both in 2008 and 2011, ulcer healing rate significantly increased, as well as the rate of minor amputation before healing. In parallel, the proportion of patients with a persisting DFU at 6 months significantly decreased (Table 6). In the 2011 audit, these rates did not significantly differ between previously participating DFCs and first-time participants ($N = 14$), except for healing after minor amputation, the rate of which was significantly lower in first-time participants (Table 6).

Variability of DFU management

We investigated the overall evolution and the variability of two quality indicators: off-loading of plantar mid-foot ulcers and revascularization of lower limbs with (sub)critical ischaemia.

Among the 17 DFCs participating in both the 2008 and 2011 audits, off-loading rate was 87.2% in 2008 ($N = 196$) and 88.8% in 2011 ($N = 196$, $p > 0.05$ *vs* 2008). In 2011, the rate among first-time participating DFCs was 86.8% ($N = 144$, $p > 0.05$ *vs* previously participating DFCs). The rates of revascularization of ischaemic lower limbs were 39.4% in 2008 ($N = 480$) and 44.0% in 2011 ($N = 514$, $p > 0.05$ *vs* 2008) and 38.2% among first-time participating DFCs in 2011 ($N = 343$, $p > 0.05$ *vs* previously participating DFCs).

Figure 1(B) and (D) show that, in 2011, two and five DFCs, respectively, were situated below the lower 2 SD control limit for the two selected quality indicators. At the median sample size of 11 plantar mid-foot ulcers, a theoretical DFC would have to score >33 percentage points below the overall off-loading rate in order to lie beyond the lower control limit and be termed an 'outlier' (Figure 1(B)). Similarly, at the median of 27 ischaemic limbs, the score would have to be >19 percentage points below the overall revascularization rate (Figure 1(D)).

Discussion

We succeeded in setting up a nationwide quality improvement initiative with high participation rates, on the basis of the principle of audit and feedback. Processes and outcomes of care among a sample of patients were recorded, and the results were discussed during information meetings and fed back to the DFCs as benchmarking graphs. The initiative has gone through three audit–feedback cycles between 2005 and 2013.

The initiative was conceptualized at a time when the Eurodiale study had already finished but before its results were published. Therefore, the lessons learned from the 14 selected DFCs participating in Eurodiale [13] did not explicitly inform the design of the first audit–feedback cycle of the present initiative. Nevertheless, the expert committee included the Belgian participant of the Eurodiale study, so practical issues experienced in Eurodiale were included at an early stage. The German system for accreditation of DFCs started in 2003 [14], and, in the recent years, there have been frequent exchanges to learn from each other's systems, for example, with regard to benchmarking and the organization of mutual visits between DFCs.

The audit methodology was gradually improved, and this was paralleled by a significant increase of data completeness. Moreover, in 2011, data completeness among DFCs participating for the first time equaled that among previously participating DFCs, possibly as a result of a clearer questionnaire and/or increased motivation among the newly recognized DFCs. We show that while there is statistical evidence that the DFUs in the audit sample were more severe than those in the total clinic population, the differences were small and unlikely to lead to biased results.

The main goal of this ongoing initiative is to stimulate quality improvement by benchmarking of DFCs. We found a significant increase of ulcer healing rates between 2008 and 2011. Scores for two key process indicators [6], off-loading of plantar mid-foot ulcers and revascularization of ischaemic limbs, did not significantly increase in the same period. This observation highlights that outcomes and processes of care are not necessarily associated [15–17]. Indeed, while we have not described all the recorded processes in this article, it might well be the case that it does not matter so much *whether* a certain care process was provided, rather than *how* it was provided (i.e. the expertise with which it was carried out). This latter aspect is obviously difficult to measure in a large-scale audit but might explain the discrepancy between processes and outcomes. Whereas process measures are more robust than outcome measures, because they rely less on patient characteristics [16], the use of outcome measures is preferred when quality of care depends highly on technical expertise and skills [15,18]. This is often the case in diabetic foot care, where skilled operators and well-organized teams are essential for successful and timely orthopaedic surgery, vascular interventions and casting.

Further research is needed to establish the reasons for the increased ulcer healing rate. A detailed analysis of patient and ulcer outcomes and their predictors was, however, beyond the scope of this article and will be published separately. For now, we will focus on the possible role of increased awareness, thanks to the recognition of the DFCs and the existence of the quality improvement initiative. First, the observation that ulcer severity at

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presentation steadily decreased across audits may explain the increased healing rate. It also suggests that diabetic foot care in primary care has improved, resulting in fewer severe DFUs presenting in DFCs, although this hypothesis remains to be tested. It is, however, plausible that recognition of the DFCs has brought increased attention to the issue of diabetic foot care and has resulted in quality improvement beyond the DFCs themselves. A second possible explanation for the improved outcomes is increased awareness to specific issues and improved knowledge among DFC team members themselves. Indeed, in addition to the information meetings organized within this quality improvement initiative, the recognized DFCs have organized, in collaboration with patient organizations, further symposia after each of the three cycles, focusing successively on off-loading, vascular interventions and infection. Although our results do not show that off-loading and revascularization were practised more often between 2008 and 2011, the information meetings and symposia may have contributed to more appropriate and skilled interventions and may thus have led to improved outcomes.

To our knowledge, this is the first initiative to provide routine benchmarking of specialized diabetic foot care (processes and outcomes) to DFCs. Compared with certain other fields, benchmarking of DFCs is challenging. First, patient volume in DFCs is usually relatively low as compared with other areas of medicine where benchmarking is used. Moreover, given the exhaustiveness of the questionnaire in this initiative (see in the following text), it was not feasible to collect the data of all patients, and a trade-off had to be made. This made it difficult to detect differences in care, because indicator scores could only be estimated with relatively low confidence, as exemplified by the funnel plot analysis in Figure 1 [19–22]. Clearly, providing benchmarking with regard to the care of acute Charcot foot is impossible given its low incidence. This does not, however, preclude the implementation of continuous and long-term quality monitoring systems *within* DFCs that would allow follow-up of foot care, for example, by using control charts [23]. Examples could be the use of a *p*-chart [23] to evaluate casting techniques by monitoring the frequency of *de novo* ulceration or an *xmr*-chart [23] for monitoring the duration of immobilization until cooling down of an acute Charcot foot. Second, given the complex pathophysiology of DFUs and acute Charcot foot, many parameters need to be collected to understand the severity and treatment of the foot problem and to predict its outcomes. Thus, many aspects of care could potentially be benchmarked, but there is no consensus as to which aspects matter most. For instance, the use of major amputation rate as a quality indicator has been criticized [24], because it depends, among other things, on disease prevalence, referral time and availability of resources. However, this can be said of *any* outcome measure, for example, also of ulcer healing rates. In time, our initiative will be able to provide guidance in this area as the association of processes to outcomes of care becomes clearer.

Although we show that benchmarking is challenging, simply collecting data and discussing the results are very meaningful endeavours from a quality improvement perspective. We agree with the guidelines from the International Working Group on the Diabetic Foot when they recommend that auditing should be part of the organization of diabetic foot care in any region [6], taking into account that the efforts required for data collection and analysis should be balanced by the expected benefits.

In our experience, the following lessons are useful for future quality improvement initiatives. (1) We have evolved from retrospective to prospective data collections, not only to improve data quality but also to highlight the importance of continuous record keeping and to further instil among data providers a sense of 'quality-thinking', something which is not necessarily the case with retrospective data collections, where data providers are gathering data for only a limited amount of time (e.g. several days a year). (2) A pilot phase is essential to arrive at an optimal questionnaire. Capturing the day-to-day reality of multidisciplinary diabetic foot care in a questionnaire is indeed challenging. After the pilot phase, we dropped or rephrased irrelevant or hard-to-interpret questions, thus simplifying data gathering.

Although the demographics and medical history of the patients in the present study were comparable with those of the Eurodiale study, the ulcers were, due to different inclusion criteria, more severe [25]. Compared to studies including less severe ulcers and/or with a longer follow-up duration [14,17,25,26], the achieved healing, amputation and mortality rates were favourable.

The rates of off-loading and revascularization in the current report were higher than among the 14 selected Eurodiale DFCs [7], although there was still room for improvement and results with regard to off-loading might be difficult to compare given the different definitions. However, as stated earlier, it remains to be established whether higher rates for key processes in DFU management, mentioned in current guidelines [6], will lead to better outcomes. The cyclical nature of our quality initiative will reveal whether improved adherence to guidelines will lead to better outcomes and, should this not be the case, whether more specific guidelines [7] or other interventions are needed.

In conclusion, it is feasible to implement a nationwide quality improvement initiative among DFCs. The current methodology yields real-life data, allowing quality

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monitoring on a national level, as well as in individual DFCs, and it affords us a better understanding of barriers to high-quality care, as well as of areas where quality improvement is possible.

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Conflict of interest

None declared.

References

1. Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J. The global burden of diabetic foot disease. *Lancet* 2005; **366**: 1719–1724.
2. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA* 2005; **293**: 217–228.
3. Ribu L, Hanestad BR, Moum T, Birkeland K, Rustoen T. A comparison of the health-related quality of life in patients with diabetic foot ulcers, with a diabetes group and a nondiabetes group from the general population. *Qual Life Res* 2007; **16**: 179–189.
4. Matricali GA, Dereymaeker G, Muls E, Flour M, Mathieu C. Economic aspects of diabetic foot care in a multidisciplinary setting: a review. *Diabetes Metab Res Rev* 2007; **23**: 339–347.
5. Prompers L, Huijberts M, Schaper N, *et al*. Resource utilisation and costs associated with the treatment of diabetic foot ulcers. Prospective data from the Eurodiale Study. *Diabetologia* 2008; **51**: 1826–1834.
6. Bakker K, Apelqvist J, Schaper NC. Practical guidelines on the management and prevention of the diabetic foot 2011. *Diabetes Metab Res Rev* 2012; **28**(Suppl 1): 225–231.
7. Prompers L, Huijberts M, Apelqvist J, *et al*. Delivery of care to diabetic patients with foot ulcers in daily practice: results of the Eurodiale Study, a prospective cohort study. *Diabet Med* 2008; **25**: 700–707.
8. Ivers N, Jamtvedt G, Flottorp S, *et al*. Audit and feedback: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev* 2012; **6**: CD000259.
9. Debacker N, Nobels F, Vandenberghe H, Van Crombrugge P, Scheen A, Van Casteren V. Organization of a quality-assurance project in all Belgian multidisciplinary diabetes centres treating insulin-treated diabetes patients: 5 years' experience. *Diabet Med* 2008; **25**: 179–185.
10. Wagner FW Jr. The dysvascular foot: a system for diagnosis and treatment. *Foot Ankle* 1981; **2**: 64–122.
11. Schaper NC. Diabetic foot ulcer classification system for research purposes: a progress report on criteria for including patients in research studies. *Diabetes Metab Res Rev* 2004; **20**(Suppl 1): S90–S95.
12. Spiegelhalter DJ. Funnel plots for comparing institutional performance. *Stat Med* 2005; **24**: 1185–1202.
13. Akhtar S, Schaper N, Apelqvist J, Jude E. A review of the Eurodiale studies: what lessons for diabetic foot care? *Curr Diab Rep* 2011; **11**: 302–309.
14. Lobmann R, Müller E, Kersken J, *et al*. The diabetic foot in Germany: analysis of quality in specialised diabetic footcare centres, 2008. Available at: http://www.woundsinternational.com/case-reports/the-diabetic-foot-in-germany-analysis-of-quality-in-specialised-diabetic-footcare-centres. Accessed October 3, 2013.
15. Mant J. Process *versus* outcome indicators in the assessment of quality of health care. *Int J Qual Health Care* 2001; **13**: 475–480.
16. Lilford RJ, Brown CA, Nicholl J. Use of process measures to monitor the quality of clinical practice. *BMJ* 2007; **335**: 648–650.
17. Taylor SM, Johnson BL, Samies NL, *et al*. Contemporary management of diabetic neuropathic foot ulceration: a study of 917 consecutively treated limbs. *J Am Coll Surg* 2011; **212**: 532–545.
18. Blumenthal D. Part 1: Quality of care – what is it? *N Engl J Med* 1996; **335**: 891–894.
19. Greenfield S, Kaplan SH, Kahn R, Ninomiya J, Griffith JL. Profiling care provided by different groups of physicians: effects of patient case-mix (bias) and physician-level clustering on quality assessment results. *Ann Intern Med* 2002; **136**: 111–121.
20. Hofer TP, Hayward RA, Greenfield S, Wagner EH, Kaplan SH, Manning WG. The unreliability of individual physician 'report cards' for assessing the costs and quality of care of a chronic disease. *JAMA* 1999; **281**: 2098–2105.
21. Scholle SH, Roski J, Adams JL, *et al*. Benchmarking physician performance: reliability of individual and composite measures. *Am J Manag Care* 2008; **14**: 833–838.
22. Kaplan SH, Griffith JL, Price LL, Pawlson LG, Greenfield S. Improving the reliability of physician performance assessment: identifying the 'physician effect' on quality and creating composite measures. *Med Care* 2009; **47**: 378–387.
23. Mohammed MA, Worthington P, Woodall WH. Plotting basic control charts: tutorial notes for healthcare practitioners. *Qual Saf Health Care* 2008; **17**: 137–145.
24. Jeffcoate WJ, van Houtum WH. Amputation as a marker of the quality of foot care in diabetes. *Diabetologia* 2004; **47**: 2051–2058.
25. Prompers L, Schaper N, Apelqvist J, *et al*. Prediction of outcome in individuals with diabetic foot ulcers: focus on the differences between individuals with and without peripheral arterial disease. The EURODIALE Study. *Diabetologia* 2008; **51**: 747–755.
26. Jeffcoate WJ, Chipchase SY, Ince P, Game FL. Assessing the outcome of the management of diabetic foot ulcers using ulcer-related and person-related measures. *Diabetes Care* 2006; **29**: 1784–1787.