

# Infrared Thermography Compared to Standard Care in the Prevention and Care of Diabetic Foot: A Cost Analysis Utilizing Real-World Data and an Expert Panel

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**Aim:** Infrared thermography (IRT) is a non-invasive technology for screening and early detection of diabetic foot. Real-world data and the Delphi technique were used to assess IRT's potential effect on typical care pathways of diabetic foot and their costs in the Finnish healthcare setting.

**Methods:** The most typical care pathways of diabetic foot were identified from national healthcare registers from 2011 to 2017. The effect of IRT in terms of avoidable care episodes was assessed by a Delphi panel including Finnish diabetic foot specialists (n=13). By combining a series of decision-analytic models, the IRT's potential effect on the costs of each pathway and their sensitivity to model assumptions were estimated.

**Results:** Hypothetical annual savings were estimated to be EUR ~1.7 million (EUR ~1.3 million–EUR ~2.5 million), constituting approximately 20% of the total annual care pathway costs examined. In the longer and more complex pathways, the application of IRT was estimated to result in notable savings while in the shorter pathways, IRT could increase costs.

**Conclusion:** Our modeling suggests that IRT could potentially reduce costs in a Finnish healthcare setting. Given our analysis, generation of robust evidence on the effectiveness of recent IRT technologies with up-to-date protocols seems appropriate.

**Keywords:** foot complication, infrared thermography, healthcare costs, cost analysis, expert panel, diabetic foot

## Introduction

Diabetic foot syndrome is a public health issue resulting in disability, reduced quality of life, and increased healthcare costs. The global prevalence of diabetic foot is over 6% and it occurs more often among men than women and people with type 2 than type 1 diabetes mellitus.<sup>1</sup> In Finland, the age-standardized incidence and prevalence of diabetic foot were 111 and 989 per 10,000 people with diabetes in 2015–2017. In the coming years, the prevalence is expected to increase due to the aging diabetes population.<sup>2</sup>

The economic burden of diabetic foot on healthcare systems is also substantial. The severity of the condition and the specifics of provided health services incorporate variability in the costs,<sup>3–6</sup> of which the latter highlights the need for country-specific studies. According to two recent Finnish studies, annual per-person costs related to diabetes foot complications were the highest of all complications, varying from 13,694 € to 17,666 € (2017 euros), while the total costs were approximately one-third of cardiovascular complications and around one-sixth of total costs of diagnosis-specific costs of complications.<sup>7,8</sup>

Infrared thermography (IRT) is a non-invasive technology used in screening and early detection of diabetic foot. IRT detects infrared radiation resulting from increased skin surface temperature induced by inflammation in the tissue. The

assessment of side-to-side and local differences in temperature can enable early detection of ulcers.<sup>9</sup> Although studies have shown successful applications of IRT in a variety of fields in medicine including diabetic foot,<sup>10</sup> conflicting evidence on its effectiveness has restricted its role to complement diagnostic information provided by other methods.

IRT has been recommended by the International Working Group on the Diabetic Foot (IWGDF) as an option to prevent ulcers, mainly based on evidence from three randomized controlled trials (RCTs) conducted in early 2000s. These studies showed large effects of IRT in the reduction of foot ulcer recurrence,<sup>11–14</sup> however, these findings have been contradicted by more recent RCTs.<sup>15–17</sup> The estimated technology and characteristics of the study setting arguably affect the effectiveness estimates. Since no consensus has yet been reached among experts on IRT's effectiveness, studies evaluating its economic efficiency are limited. The lack of evidence is the most probable reason for the rather low adaptation of IRT to routine care, which is also the case in Finland.

This ex-ante study assessed the effects of IRT on typical care pathways of diabetic foot and their costs when applied at regular check-ups. The assessment was made from a healthcare perspective and was based on care pathways identified from population-wide real-world data. Since IRT is not yet used regularly and patient data are therefore not available, its effects on the pathways were assessed using the Delphi method.<sup>18</sup> Based on the expert panel's opinion, the effect of IRT on each current care pathway was estimated and results were illustrated using decision analytic models. More specifically, we aimed to assess how the application of IRT 1) would affect the current care pathways and 2) would affect the costs of current care pathways, if applied as a standard practice.

This study provides preliminary estimates of IRT's potential effect on current care pathways and their costs in a real-world setting. These estimates provide useful information for healthcare professionals and decision-makers involved in diabetic foot care to develop treatment and care pathways for diabetic foot. Furthermore, the estimates could guide the design of more controlled experiments on IRT's effectiveness and cost-effectiveness.

## Materials and Methods

The phases of the study are illustrated in [Figure 1](#). The first phase involved the identification of 10 typical care pathways from national healthcare registers. Steps 1.1 and 1.2 have been described in detail in.<sup>19</sup> In the second phase, 10 randomly sampled care pathways were presented to an expert panel, which assessed the effect of IRT on these pathways. Based on these assessments, hypothetical pathways were constructed including potential effects and additional cost of the IRT procedure. In the third phase, original and hypothetical pathways and their costs were compared to quantify the potential effect of IRT on the pathways. The study was carried out in adherence to Recommendations for the Conducting and Reporting of Delphi Studies (CREDES) and Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022).<sup>20,21</sup>

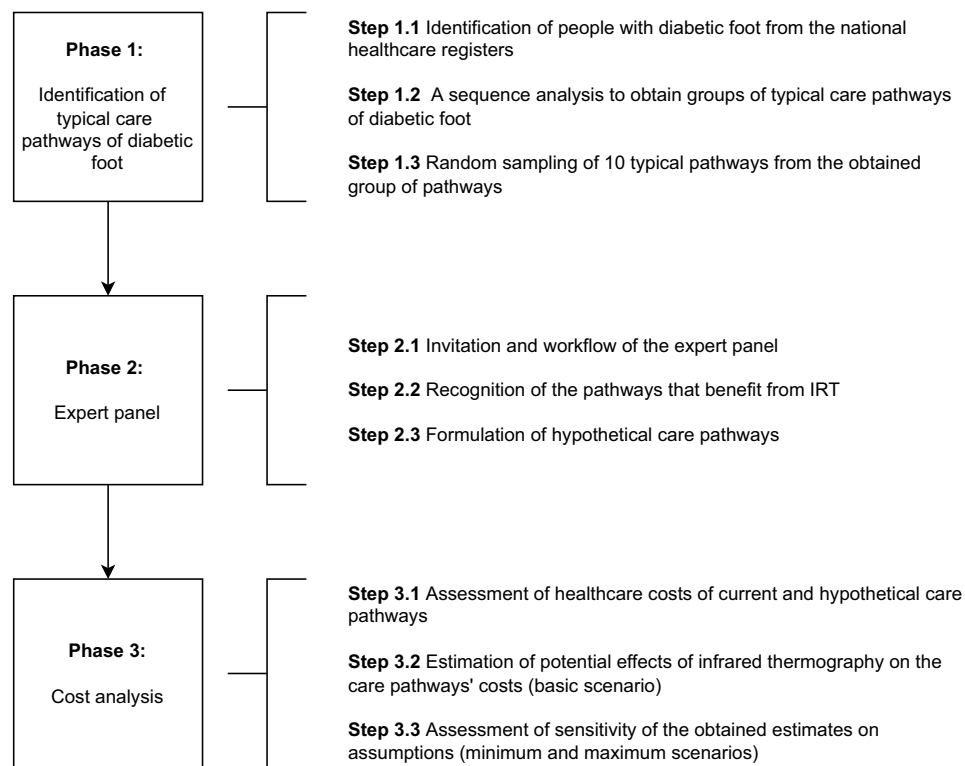
## Identification of Typical Care Pathways of Diabetic Foot (Phase I)

### Study Population

The study was based on the Diabetes in Finland (FinDM) cohort that comprised all patients with diagnosed diabetes mellitus in Finland between 1964 and 2017.<sup>22</sup> For each patient, data included information on health service use in both primary health care (PHC) and specialized health care (SHC), reimbursed costs of medication, diabetes (type, date of diagnosis) and date of birth. In Step 1.1 ([Figure 1](#)), patients with initial diabetic foot diagnoses ([Supplementary Table 1](#)) between 2011 and 2016 ( $n = 63,900$ ) were identified from the cohort. The study population was further restricted to patients who had a full two-year follow-up ( $n = 41,635$ ) starting from the initial diabetic foot diagnosis.

### Sequence Analysis

In Step 1.2 ([Figure 1](#)), the care pathway of the initial foot-related diabetes complication was defined for each patient based on their health service use. Each care pathway was restricted to diabetic foot care episodes. A sequence analysis was used to define groups of similar pathways.<sup>19,23,24</sup> In the analysis, each care pathway was represented as a sequence of equal number of states with each state representing either a care episode or the absence of care episodes. A hierarchical clustering algorithm was then applied to identify groups of similar sequences (group of pathways).



**Figure 1** Study phases.

### Selection of Ten Typical Pathways

Since significant heterogeneity remained within each identified group of pathways, they were further divided into subgroups based on the number and type of care episodes they contained [20]. In each group of pathways, the two largest subgroups comprised the majority of pathways. Thus, nine pathways were randomly selected from the two largest subgroups within each group of pathways (Step 1.3, Figure 1). By removing the outlier pathways, the heterogeneity in the examined pathways could be reduced with only a modest decrease in representativeness. A care pathway involving an amputation was also included, since despite amputation being quite an infrequent event (present in 2% of all pathways), its costs and effects on quality of life are substantial.<sup>25</sup> The amputation pathway was randomly selected from all pathways including amputation.

### Expert Panel (Phase 2)

The Delphi method was used to assess the effect of IRT on typical care pathways. The method aims to achieve consensus among experts, in this study the diabetic foot specialists, on a particular issue to provide estimates in cases when more robust methods are not feasible.<sup>18</sup>

#### Invitation and Workflow of the Expert Panel

In Step 2.1 (Figure 1), an expert panel was invited to estimate the effect of IRT on the care pathways (the Delphi method).<sup>18</sup> Eight physicians and five podiatrists were invited to the panel, a total of 13 experts. Podiatrists and physicians from both university and central hospitals and non-governmental organizations were invited with the aim to cover all relevant specialties involved in the multidisciplinary care of diabetic foot: diabetology, physiatry, vascular surgery, orthopedics and plastic surgery. Most of the experts had previous knowledge of IRT, although not wide experience. While on the panel, they did not represent their employers. They were not affiliated with the study funder and received no compensation. The expert panel were asked to respond anonymously to two rounds (December 2020 and January 2021) of an electronic questionnaire.

## Recognition of the Pathways Benefiting from IRT

In the first round, diagrams of 10 typical care pathways (Step 2.2, [Figure 1](#), [Supplementary Figure 1a](#) and [b](#)) were presented to the panel together with a description of the technology and its implementation. It was assumed that IRT would take place during an annual routine check-up and no additional healthcare visit was necessary.

Specifics of the care pathways included care episodes and related ICD-10 codes ([Supplementary Table 1](#)), the duration and sector of care (PHC or SHC), time between each care episode and patient characteristics (age, diabetes duration, whether or not the patient was on insulin medication and had late-stage complications). Each patient was considered to belong to IWGDF risk class 2 or 3.<sup>26</sup> For each pathway, the panel was asked to assess:

1. If IRT of the feet was performed on an annual basis, what is the probability that the first occurrence and care episodes following this could be avoided?
2. In addition to IRT, what other kinds of examination/diagnostic methods would be required?
3. How important is the regular application of IRT in this care pathway after the first contact?
4. For care pathways 5, 6, and 10: If IRT was performed after the first procedure in the care pathway, what is the probability that the first occurrence and care episodes following this could be avoided?

In the second round, six care pathways were presented to the panel. Based on the responses to the first round, these six pathways were most affected by IRT (at least 30% probability of avoiding the first care episode). For each care pathway, a summary of responses from the first round was given. In this way, the respondents could adjust their opinion based on the responses of other experts (attempt at achieving consensus).<sup>18</sup> The remaining variation was illustrated by sensitivity analyses. In the second round, question 2 was not included; however, two additional questions were asked:

1. How often (how many times per year) should IRT be performed in this pathway in the future?
2. How reliably the aforementioned items can be assessed based on the information provided in the questionnaire (1 not at all reliable, 5 very reliable)?

In both rounds, respondents were asked to give justifications for their responses, although that was not compulsory.

## Formulation of Hypothetical Care Pathways

In Step 2.3, the potential effect of IRT on the care episodes (avoidance of subsequent care episodes) on the six typical care pathways was illustrated using tree diagrams ([Figure 1](#)). In the diagrams, each branch represents a hypothetical care pathway and was associated with the probability of the pathway occurring together with a simplified description of the care episodes in the pathway (level of care and length of stay) and associated costs.

## Cost Analysis (Phase 3)

### Assessing the Costs of Current and Hypothetical Pathways

Care pathway costs included the costs of outpatient and inpatient care episodes in both public PHC and public and private SHC, as well as the procedures performed. Moreover, the costs included medication administered during care episodes.

The pathway costs were calculated (Step 3.1) based on the expense information in healthcare registers and using the national unit costs (2011) reported by the Finnish Institute for Health and Welfare.<sup>27</sup> A detailed description of costing of care episodes is described in detail.<sup>19</sup> The cost of a hypothetical pathway comprised the cost of each care episode in that particular pathway, the cost of the IRT procedure and the cost of an additional podiatrist visit.

The cost of an IRT procedure was calculated based on the acquisition cost and the actual capacity estimate. The acquisition cost was based on two available technologies by a Finnish manufacturer (Thermidas Oy, Tampere, Finland): a clinical IR system and a handheld IR system with the annual costs of EUR 9000 and EUR 4000, respectively, assuming a service life of 5 years.<sup>28</sup> The actual capacity estimate was based on a university hospital setting. Based on a specialist's opinion, we assumed an annual maximum capacity of 4800 procedures and an annual actual capacity of 960 procedures

(20% of maximum capacity). Consequently, an additional cost of EUR 9 and EUR 4 per procedure was applied for a clinical IR system and a handheld IR system, respectively.

The Finnish Current Care Guidelines recommend at least one annual visit to a podiatrist for patients in risk class 1, 2 or 3.<sup>26</sup> Assuming that a follow-up by a podiatrist was necessary after a positive finding using IRT, the cost of podiatrist visit(s) was included in the hypothetical pathways. The cost of the visit was based on the national average cost (EUR 90).<sup>27</sup>

All monetary values are presented in 2017 euros (last year of the study) and converted using the price index for public expenditure provided by Statistics Finland.<sup>29</sup> The total costs were further converted into US dollars using an exchange rate of 1.1993 (31 December 2017).<sup>30</sup>

### Estimation of Effects of IRT on Pathways' Costs

In Step 3.2 (Figure 1), we estimated the effect of IRT on each pathway's costs by calculating the expected cost of each hypothetical pathway and by reducing the cost of the corresponding current care pathway (treatment as usual) to obtain pathway-specific estimates (IRT's effect). The expected cost was calculated for each pathway as follows: the cost of each hypothetical pathway (branch of the tree) was multiplied by its probability of occurrence and the resulting costs were added. Each pathway-specific difference in costs was then multiplied by the number of pathways in the subgroup from which the pathway was originally sampled to obtain an estimate of total effect. The sum of these total effects represented the potential savings that could have been achieved in typical care pathways of diabetic foot that has started between 2011 and 2015.

### Sensitivity Analysis

There was uncertainty associated with each hypothetical pathway's probability of occurrence, the necessary number of additional visits to a podiatrist and additional examinations, all of which have an impact on the estimated effect. Furthermore, we incorporated variation in costs related to the choice of technology.

Since IRT is not a sufficient method for the diagnosis of diabetic foot, the diagnosis should be confirmed with additional examinations. The necessity of these additional examinations differed by care pathways and by respondent. Thus, the sensitivity of costs to the number of necessary additional examinations was assessed. Out of the suggested additional examinations, it was assumed that plain (x-ray) film, magnetic resonance imaging (MRI), angiography and electroneuromyography (ENMG) would create additional costs of EUR 140, EUR 1217 and EUR 674, respectively.<sup>27,31</sup>

To address the sensitivity of the estimates to various assumptions (Step 3.3, Figure 1), we created three scenarios for the potential effect: basic, minimum and maximum scenarios, which differed in the aforementioned factors (Table 1). In the minimum scenario, the probability of each additional examination was defined as the proportion of respondents suggesting the particular examination and the total number of respondents who answered the question (Supplementary Table 2).

All analyses were conducted using R statistical software (version 4.0.3).<sup>32</sup>

## Results

### Typical Care Pathways (Phase I)

A total of 41,640 people with initial foot-related diabetes complications and at least 2 years of follow-up was identified during the study period. Sequence analysis resulted in six groups of typical care pathways that differed notably in type and number of pathways. The results of this study phase are reported and discussed in detail elsewhere.<sup>19</sup>

**Table 1** Three Scenarios for Potential Effect of Infrared Thermography on Current Care Pathways and Related Assumptions

	Pathway Probability	IRT Cost, EUR	Number of Podiatrist Visits	Additional Examinations
Basic scenario	Median of probabilities	7	1.5	No
Minimum scenario	1st quartile of probabilities	9	2	Yes
Maximum scenario	3rd quartile of probabilities	4	1	No

**Note:** EUR = 2017 euro.

## Assessments of the Expert Panel (Phase 2)

In the first round, nine respondents (75%) filled the questionnaire. Four of the respondents were physicians and five of them were podiatrists ([Supplementary Table 3](#)). With regard to questions 1 and 4, the assessed probabilities varied notably between the respondents. Six out of 10 care pathways had a median probability of at least 30% and were selected for the second round. These pathways represented 25% of all original care pathways. With regard to question 3, the median of importance of regular IRT was 3 or 4 for six care pathways and 1 or 2 for four care pathways (scale 1–5, higher values indicating higher importance). The panelists stated that optimal benefits would be achieved if IRT were performed at least once per year. Thus, a question about the optimal frequency of IRT was added to the questionnaire in the second round.

In the second round, 11 respondents (85%, 6 physicians and 5 podiatrists) filled the questionnaire ([Supplementary Table 3](#)). The variation of probabilities of Questions 1 and 4 were lower compared to the first round. In all six care pathways, IRT was considered important (a median of at least 3, Question 3). The panelists' assessments of the optimal frequency of IRT varied from 1 to 4, 1 to 6 or 1 to 10 times per year, depending on the pathway (Question 5). In addition to IRT, the panelists described many other examination/diagnostic methods (Question 2, [Supplementary Table 4](#)). All question-specific responses were utilized for analyses in both rounds, regardless of whether the respondent had returned an incomplete questionnaire.

Further justifications from both rounds emphasized two major benefits of IRT: first, discovery of areas with excess load at an early stage of the condition could prevent its deterioration if appropriate actions were taken and second, observation in an IRT image could support the actual diagnosis of the condition. The panel also pointed out that when carried out in PHC, IRT could prevent visits to secondary health care, motivate patients to engage in better self-care and support the assessment of the suitability of diabetic footwear. Regarding pathways in which the clinical status was assessed to be clear, IRT would not provide any additional benefits (eg, fungal nail infection and hallux valgus). The justifications were similar in both rounds. The respondents stated that questions assessments could be made reliably (Question 6, [Supplementary Table 3](#)).

Based on the responses regarding the current care pathways presented to the expert panel in the second round, we formulated hypothetical pathways that would result from the application of IRT within the current pathways ([Figure 2](#)).

## Effect of IRT on Pathways' Costs: Current vs Hypothetical Care Pathways (Phase 3)

The current care pathways presented to the expert panel in the second round ([Table 2](#)) differed notably in terms of number of care episodes and costs ([Table 2](#)). The size of the patient subgroups that each pathway represented varied from hundreds to a few thousand.

### Basic Scenario

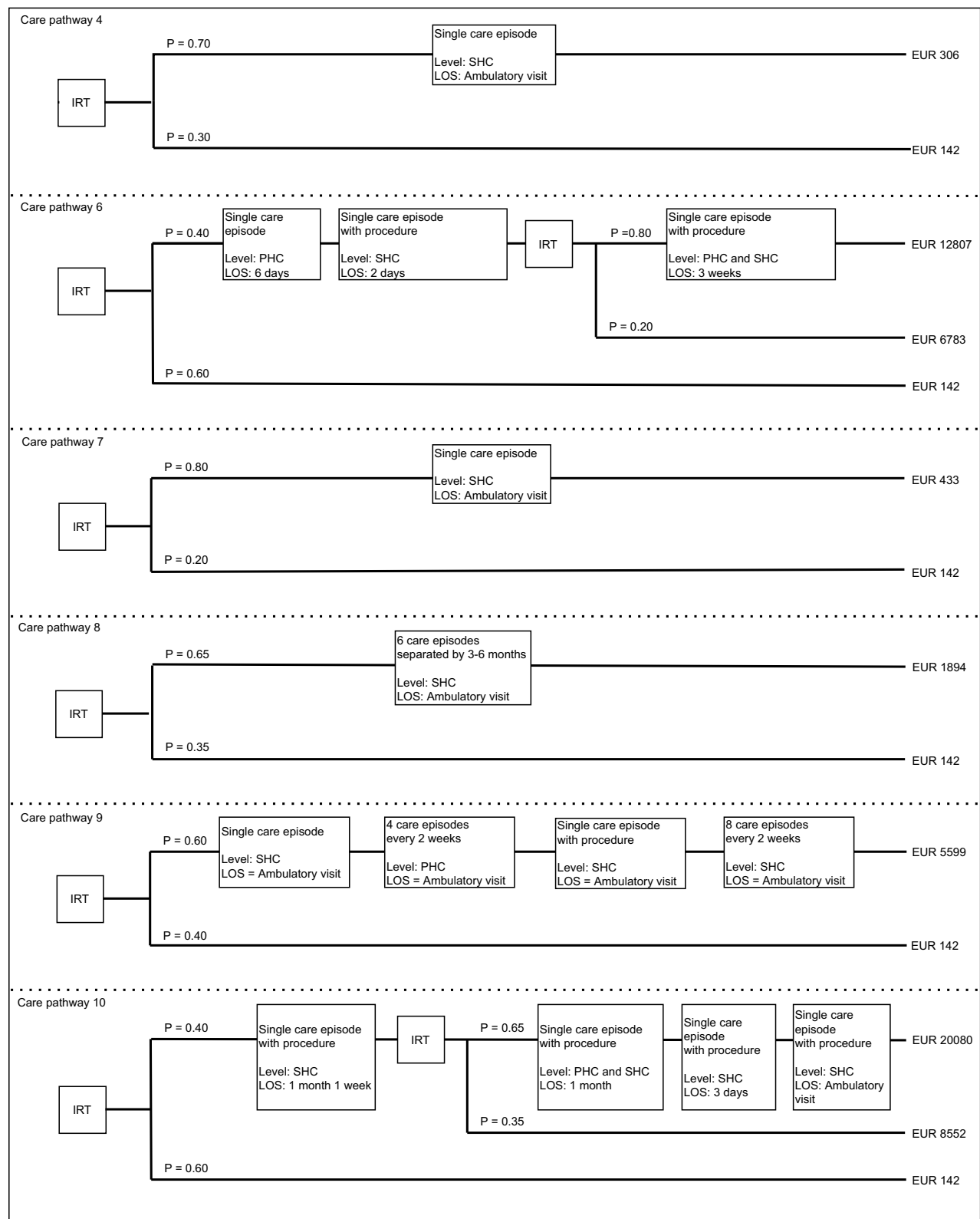
Within this basic scenario, the estimated costs of hypothetical care pathways were notably lower compared to current care pathways ([Table 2](#)) among longer and more complex care pathways (amputation, long neuropathy, nail and ulcer pathways). At highest, costs were approximately 70% lower (ulcer pathway). Among shorter pathways, the costs of hypothetical pathways (callus and short neuropathy pathways) were higher compared to current pathways (50% increase at highest, callus pathway).

The potential total effect of IRT on pathways' costs was estimated to be approximately EUR 12 million during the study period ([Table 2](#)). The largest savings were estimated in the amputation pathway, approximately EUR 8 million, while the highest cost increase was associated with the callus pathway (EUR 0.6 million).

### Minimum and Maximum Scenarios

The estimated potential effects of IRT were sensitive to the assumptions made ([Table 3](#)). In the minimum and maximum scenarios, the potential total savings were approximately EUR 9 million and EUR 18 million, respectively. In the maximum scenario, the costs of hypothetical care pathways were 4–75% lower than in the basic scenario. In the minimum scenario, the costs of hypothetical care pathways were 20–36% higher compared to the basic scenario.





**Figure 2** Hypothetical care pathways including infrared thermography and their costs. Current care pathways are presented in [Supplementary Figure 1a](#) and [b](#).

**Notes:** Hypothetical care pathways are presented in a simplified form including the probability of the pathway occurring, the number, length of stay (LOS) and healthcare level on which care is provided and cost of the pathway.

**Abbreviations:** PHC, primary health care; SHC, specialized health care; IRT, infrared thermography; LOS, length of stay.

**Table 2** Potential Effects of Infrared Thermography on Costs of Pathways That Started Between 2011 and 2015 (Basic Scenario)

Pathway	Subgroup Size n (%)	Current EUR/Pathway	Hypothetical EUR/Pathway	Savings EUR/Pathway	Overall Savings EUR
4: Callus	6497 (65)	164	256	−92	−597,724
6: Amputation	998 (10)	12,523	4726	7797	7,781,406
7: Neuropathy, short pathway	1185 (12)	291	375	−84	−99,540
8: Neuropathy, long pathway	797 (8)	1752	1280	472	376,184
9: Nail	270 (3)	5457	3416	2041	551,070
10: Ulcer	309 (3)	19,796	6503	13,293	4,107,537
Total	10,056				12,118,933

Note: EUR = 2017 euro.

**Table 3** Minimum (Min) and Maximum (Max) Scenarios of Infrared Thermography's Potential Effect on Costs of Pathways That Started Between 2011 and 2015

Pathway	Subgroup Size	Hypothetical Pathway EUR/Care Pathway		Savings EUR/Care Pathway		Overall Savings EUR	
	n (%)	Min	Max	Min	Max	Min	Max
4: Callus	6497 (65)	308	237	−144	−73	−935,568	−474,281
6: Amputation	998 (10)	6092	1239	6431	11,284	6,418,138	11,261,432
7: Short neuropathy	1185 (12)	480	94	−189	197	−223,965	233,445
8: Long neuropathy	797 (8)	1610	1235	142	517	113,174	412,049
9: Nail	270 (3)	4629	2367	828	3090	223,560	834,300
10: Ulcer	309 (3)	8514	2742	11,282	17,054	3,486,138	5,269,686
Total	10,056					9,081,477	17,536,631

Notes: Minimum (min.) and maximum (max.) refers to scenarios in which values of uncertainty factors (IRT cost, number of podiatrist visits and additional examinations) led to the least favorable and the most favorable outcomes in terms of potential effects. EUR = 2017 euro.

Regardless of scenario, savings could not be achieved with the callus pathway, while savings remained notable in other pathways (excluding short neuropathy).

## Discussion

In this study, the effects of IRT on the typical care pathways of diabetic foot identified from population-wide real-world data were assessed by an expert panel. The potential effects on each pathway's costs were then estimated utilizing decision analytic models.

Overall, the expert panel assessed that by using IRT, care episodes could be avoided in six out of 10 care pathways (callus, amputation, neuropathy, nail and ulcer pathways). These six care pathways represented approximately 25% of all identified pathways. Common to all six pathways was that the clinical status of patient on each pathway was not considered clear by some respondents, and therefore IRT would provide additional benefit. This was not the case with other care pathways (eg, fungal nail infection and hallux valgus), which were assessed not to benefit from IRT.

Most recent assessments of IRT's effectiveness include two large RCTs,<sup>16,17</sup> that with higher statistical power, have contradicted previous positive estimates.<sup>12–14</sup> Nonetheless, their focus has been entirely on assessing the feasibility of IRT in avoiding diabetic ulcer recurrence using technology and treatment protocol that differs to a large extent from those of this study. Based on the expert panel's assessment, we estimated that regular use of IRT could prevent 60% of the ulcer pathways that would result to pathway-specific saving of over EUR 13000 and total savings of over 4 million euros in the Finnish healthcare system. However, those results are not directly comparable due to differences in study design.



In total, the application of IRT was assessed to result in notable total savings with regard to the six care pathways. Longer care pathways contributed largely to the total savings, while in the Callus pathway application of IRT was estimated to increase costs due to additional examinations and visits to a podiatrist.

By dividing the total savings by number of years in the study period, we arrived at an average annual saving of approximately EUR 1.7 million (USD 2.1 million) in healthcare costs between 2011 and 2017, totaling up to 18% of the costs of the examined care pathways in this study. The savings would be due to care episodes and related expensive procedures that could be avoided by early detection of problematic areas using IRT. The savings for pathways that were not considered typical (37%) could not be assessed.

To date, cost studies or cost-effectiveness analyses of IRT are limited, to our knowledge, to a single modeling-based study from USA comparing use of IRT in addition to standard care compared to standard care alone.<sup>33</sup> Based on a decision tree analysis, Brooks et al estimated annual per-patient savings of over USD 8000 and total savings of USD 38593 per additional ulcer case. Our estimate concerning the Ulcer pathway was notably more conservative (EUR 13293). Nevertheless, studies differ profoundly in terms of technology: in our study, the IRT was applied by a healthcare professional in a healthcare setting compared to remote foot temperature monitoring technology in the US study.<sup>33</sup> Nevertheless, the study has faced critique on both its assumption of potential effectiveness and costs of treatment of ulcer<sup>34</sup> and further assessments are welcomed.

Our estimates were sensitive to the modeling assumptions, and this sensitivity was characterized by the minimum and maximum scenarios. These alternative scenarios assumed different values for the most important uncertainty factors and reflected situations that were most favorable and least favorable with respect to effects of IRT. Overall, all scenarios resulted in savings ranging from 18% to 23% of total costs. Savings were confined to longer pathways, regardless of scenario.

The modeling assumptions deserve further scrutiny. First, the effects of IRT were based on assessments of the expert panel (n=13). Despite being positive towards application of IRT, the assessed probability in each pathway had large variability within respondents. We are not sure, however, if this variability could be reduced by increasing the panel size, since the number of foot care experts with knowledge or experience on IRT in Finland is limited. Nevertheless, the panel comprised representatives from all relevant specialties involved in treatment of diabetic foot and a response rate as high as 85% was achieved, while 77% of panelists completed the questionnaire. We have no reason to assume that there would be a non-response bias between the respondents and non-respondents. However, since the number of panelists was moderate, subgroup analyses, for example, between panelists with and without IRT experience, were not possible. The panel's work was based on typical care pathways identified from population-wide real-world data, which strengthens the usability of the panel's work.<sup>35</sup>

Second, there are several IRT technologies available with evidence on their effectiveness, ranging from technologies applied in a clinical setting to technologies applied by a patient at home.<sup>16,17</sup> We depicted a scenario with a technology applied in a university hospital setting by a foot care specialist and the additional cost of IRT was determined based on two such technologies available in Finland. Naturally, additional cost of the procedure may differ to some extent in other settings. We want to emphasize that the expert panel was not asked to assess these particular products but instead the technology overall in a given setting. In addition, several other factors such as the duration of the procedure and who performs it (including interpretation of findings) affect the total cost. As appropriate values could not be found on these factors, they were not considered in our calculations.

Third, the expert panel assessed that after a positive finding, in part of the care pathways clinical examination was sufficient, while in other, multiple additional examinations and diagnostic methods were required. Confirmatory examinations naturally increase the cost of a care pathway, which was characterized using the minimum scenario. If the IRT becomes a more established practice, these uncertainty factors will be easier to assess.

The analysis was conducted from a healthcare perspective and aimed to serve decision-makers involved in treatment of diabetic foot. Therefore, some significant cost items were excluded from the analysis; social care (mainly care for older people), rehabilitation costs, direct and time costs to patients and their families, as well as productivity losses<sup>36</sup> were not considered. Further studies hopefully clarify their role.

The analyses were based on reliable national, ie, population-wide, registers including all patients with a diabetes diagnosis in Finland,<sup>22,37</sup> which is a major strength of the study. From this extensive dataset, we were able to extract

a wide array of typical care pathways using sequence analysis.<sup>19</sup> These real-world pathways represented healthcare use related to different foot-related complications comprising real-world variation in patient characteristics, thus providing a wide perspective on IRT's potential. Most of the published RCTs to date have focused on ulcer recurrence with restricted patient population. In our study, ulcer pathways represented only 3% of all pathways. In practice, investigation using real-world data may be the only feasible option to assess IRTs effectiveness and cost-effectiveness with regard to some of the foot complications.

The modeling-based approach required multiple assumptions to be made, which relied heavily on the clinical expertise in the research group. If IRT becomes a more established practice, their assessment may be more strongly supported by data. We found it challenging to estimate the number of annual IRT procedures necessary to detect changes in skin temperature effectively and therefore we based our estimate on typical frequency of patient visits in routine care of patients with diabetes. The expert panel suggested a range of 1 to 10 IRT procedures per year, depending on the pathway, while published RCTs have typically applied daily or monthly monitoring of skin temperature.<sup>15–17</sup> Very high intense monitoring in a clinical setting may not be a feasible practice in many of these pathways. Nevertheless, the modeling-based approach is useful in estimating the potential of IRT in a Finnish healthcare setting and guiding setups of future effectiveness and cost-effectiveness studies.

A factor largely determining the success of IRT is patients' compliance with the long-term monitoring, which depends highly on its frequency and the applied technology. The issue of compliance is emphasized among patients with diabetes, due to often already high load of monitoring and previous studies have reported low adherence to technologies requiring daily self-monitoring.<sup>17</sup> This study assumed that IRT was applied mainly at routine check-ups by a healthcare professional, which could possibly result in higher concordance among patients. Factors affecting patients' compliance are an important topic for future research.

As a major shortcoming, the data did not cover care given in private outpatient and occupational health care. However, these sectors contribute only little to the treatment of diabetic foot in Finland, and therefore introduce only minimal bias in representativeness of the examined care pathways. In addition, we lacked data on some relevant cost items. Even though the costs of reimbursed outpatient medication were available in the registers, it was not possible to specifically identify which forms of medications were prescribed to treat the complications in question. In Finland, outpatient medication expenses are partly covered by the Social Insurance Institution of Finland and partly by patients. Thus, the costs do not entirely devolve on the healthcare system. Finally, national databases do not comprise information on the use and costs of diabetic footwear. The absence of such knowledge may significantly impact the cost estimates of shorter pathways, since in some cases the cost of diabetic shoes may exceed the cost of the whole pathway.

This modeling study contributes to the treatment of diabetic foot by providing first assessment of IRT's potential as a standard procedure in the prevention and treatment of diabetic foot in the Finnish healthcare setting. Moreover, it is one of the rare studies assessing the IRT's effect on costs. Our approach provides an alternative point of view to published RCTs by examining a wider set of conditions based on real-world data. Based on our estimates, IRT could provide savings in most of the typical care pathways of diabetic foot and the results suggest that the evaluation of IRT should proceed into more controlled studies in a Finnish healthcare setting, when feasible. Further evidence on IRT's effectiveness and cost-effectiveness, however, is necessary for the decision on whether IRT should be adapted as part of the standard practice.

To effectively prevent a condition from deteriorating, it needs to be detected at an early stage.<sup>38</sup> Therefore, a major patient group that could benefit from IRT are patients with diagnosed loss of protective sensation (LOPS) who have not yet developed an ulcer. IRT could then be applied in PHC and visits to SHC and expensive procedures could potentially be avoided. In case of detection of complication delays, overall costs could increase. Ensuring a functional care pathway after a positive finding is crucial.

In case the application of IRT becomes more common, prospective studies using also individual-level outcome data are needed. In addition to resource use and costs, also benefits in terms of quality of life should be considered. Only recently, a procedure code indicating IRT became available in Finland that enables healthcare professionals to associate an IRT procedure to a care episode. This will hopefully enable monitoring of technology's adaptation as part of standard care and future real-world studies of its effectiveness and cost-effectiveness using national healthcare registers.

## Conclusions

In conclusion, our model suggested that hypothetical annual savings of more than EUR 1.7 million could be achieved by using IRT as a standard procedure. Despite the estimates being somewhat sensitive to the assumptions of the model, annual savings were achieved in all scenarios (1.3 to 2.5 million euros). This study contributes by providing insights for healthcare professionals and decision-makers involved in diabetic foot care when considering and implementing treatment methods. As the prevalence of diabetic foot is expected to increase in the coming years, imposing an escalating burden on healthcare systems, continuous follow-up of costs and effectiveness of diabetic foot treatments is essential.

## Abbreviations

ENMG, electroneuromyography; FinDM, Diabetes in Finland study; ICD-10, International Classification of Diseases 10; IRT, infrared thermography; LOS, length of stay; MRI, magnetic resonance imaging; PHC, primary health care; SHC, specialized health care.

## Data Sharing Statement

The data that support the findings of this study are available from the Finnish Institute of Health and Welfare. However, restrictions apply to the availability of these data, which were used under license for the current study and are therefore not in the public domain. However, the data are available from the authors upon reasonable request and with the permission of the Finnish Institute of Health and Welfare (author to contact: MA, [martti.arffman@thl.fi](mailto:martti.arffman@thl.fi)).

## Ethics Approval and Informed Consent

The FinDM study protocol was approved by the Research Ethics Committee of Finnish Institute for Health and Welfare (decision number 2018/§787). Permission to use the register data was obtained from the competent register authorities (Finnish Institute for Health and Welfare, Social Insurance Institution of Finland, Statistics Finland, Finnish Centre of Pensions, Finnish Kidney and Liver Association). Informed consent was not required as this is a retrospective register-based study. Study data was pseudonymized before use.

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## Disclosure

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