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National Board of Health

DIABETIC FOOT ULCERS

– a health technology assessment

Summary

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Summary

The Diabetes Steering Committee[1] of Denmark's National Board of Health initiated this health technology assessment of the diagnosis and treatment of people with diabetic foot ulcers. The Committee discussed the need for health technology assessment related to diabetic foot ulcers in November 2008 and agreed that foot ulcers require a special focus, since clarity is lacking on the best way to organise diagnosis and treatment in Denmark.

This health technology assessment should thus provide a basis for assessing whether the organisation of diagnosis and treatment needs to be changed and for preparing national clinical guidelines for this field. This report focuses on providing relevant, comprehensive evidence-based knowledge on:

- the outcome of diagnosis and treatment for diabetic foot ulcers
- how patients experience the disease and the organisation of diagnosis and treatment
- the current way diagnosis and treatment are organised and how they can be appropriately organised in the future, and
- the economic costs of diagnosing and treating people with diabetic foot ulcers.

The reasons for this special focus on how diagnosis and treatment are organised include the fact that the organisation of this field is extremely complex. Physicians from several medical specialties, including orthopaedic surgery, vascular surgery, internal medicine, endocrinology, dermatovenerology, diagnostic radiology and family medicine, participate in treating people with diabetic foot ulcers in Denmark. In addition, other health care professionals participate, such as podiatrists, physical therapists and nurses. People with diabetic foot ulcers in Denmark are thus cared for in collaboration between several medical specialties and other health professionals across primary and secondary health care and the public and private sectors. This poses great demands on the organisation and on the communication needed to achieve positive outcomes for each person. This also poses great demands on the people with diabetic foot ulcers and how they manage their own ulcers. Thus, patients must not only deal with the foot ulcer but also relate to a complex system of therapists and a course of disease that is often long term simultaneously with managing and mastering the underlying chronic disease: diabetes.

Denmark's administrative regions and municipalities carry out this complex task of diagnosis and treatment in various ways, and there is no consensus on the ideal level of specialisation or how centralised or decentralised the treatment should be carried out. A 1994 report by Denmark's National Board of Health on the treatment of people with diabetes in Denmark and a health technology assessment in 2003 on type 2 diabetes briefly describe prevention and treatment related to diabetic foot ulcers, including organisation in multidisciplinary teams, but an overview is lacking of the extent to which this form of organisation has been implemented in practice. Further, knowledge is needed on how this field is organised as a whole.

The expenditure for treating people with diabetic foot ulcers comprises a considerable proportion of the money used in Denmark for treating people with diabetes. Studies from comparable countries indicate that expenditure for treating people with foot ulcers comprises about 25-50 % of the total inpatient expenditure for people with diabetes. The treatment costs vary, however, and depend on the process of treatment and the complexity of the foot ulcer, but amputating part or all of the foot or leg is quite expensive.

1 The task of the Diabetes Steering Committee is to provide broad scientific guidance to Denmark's National Board of Health on diabetes to contribute to appropriate trends generally and sustained improvement of quality in this field.

Purpose

The purpose of this health technology assessment is to critically assess the diagnosis and treatment of people with diabetic foot ulcers with the aim of indicating opportunities for organising this field more appropriately. This critical assessment includes analysing the following topics:

- The chapter focusing on technology assesses the outcome of many technologies used in diagnosing and treating people with diabetic foot ulcers. In addition, the outcome of telemedicine and multidisciplinary teams is assessed.
- The chapter focusing on patients investigates the characteristics of people with diabetic foot ulcers and how they experience their symptoms, with the aim of determining how these factors influence the needs of these people for organisation in this field. In addition, the opportunities and barriers people with diabetic foot ulcers experience in relation to organisation are assessed.
- The chapter focusing on organisation assesses the current organisation of diagnosis and treatment and the barriers and opportunities regarding organisation with the aim of outlining proposals that can contribute to appropriate organisation in this field.
- The chapter focusing on economics assesses the economic costs to society of diagnosis and treatment and discusses the potential economic effects of proposals to change the organisation of diagnosis and treatment.

Target audience

The main target audience for this report is the Diabetes Steering Committee and the National Board of Health, which initiated the assessment. Nevertheless, the report is also relevant for everyone involved in some way in planning in this field or working with diagnosis and treatment related to diabetic foot ulcers.

Definition and delimitation

This report defines diabetic foot ulcers as:

'lesions of the skin on the foot of a person who has diabetes mellitus'.

Diabetic foot ulcers typically arise on a foot with poor nerve signalling and poor circulation, often caused by harmful pressure on parts of the foot.

This report limits diagnosis and treatment to include the process that begins when a foot ulcer is discovered. Thus, the report does not focus on prevention or follow-up treatment. These aspects are important, but assessing the organisation of diagnosis and treatment is a complex and comprehensive task, and the report could not incorporate additional perspectives.

Data and methods

Systematic literature searches were conducted to investigate the questions related to technology, patients, organisation and economics in this report. The analysis only includes studies considered to be relevant and of sufficiently high quality based on critical assessment of the literature. In relation to assessment of patient, organisation and economy primary data collection and analysis was carried out. The methods used are described in detail in the individual chapters and the annexes.

Technology

The analysis of technology answers the following questions.

- What are the outcomes of technologies for diagnosis in relation to diabetic foot ulcers?

Few studies have described the diagnosis of infection, angiopathy and neuropathy in relation to diabetic foot ulcers, and the evidence related to the technologies assessed is therefore lacking, weak or, in very few cases, moderate. The technologies for diagnosing infection are especially poorly evidence-informed and range from having no to weak evidence on outcomes. Moderate evidence supports positive outcomes for the two technologies for angiopathy, peripheral (toe) blood pressure measurement with a strain-gauge technique and the Seldinger technique for angiography. These two methods of testing are thus important in assessing the circulation in connection with diagnosis. For diagnostic technologies related to neuropathy, moderate evidence supports the effectiveness of two important clinical tests: biothesiometry testing and monofilament testing. These two technologies are therefore fundamental in clinical practice. The evidence base for the other technologies related to diagnosing infection, angiopathy and neuropathy is weak and inadequate.

- How effective are the technologies for treating people with diabetic foot ulcers?

The assessment of outcomes in this field is based on very few randomised controlled trials. This means that the evidence base for optimal treatment is mostly absent or weak, and only moderate to good in a few cases. The evidence on outcomes in infection treatment is weak or lacking. Infection retards wound healing and may lead to amputation. Infections should therefore be immediately treated with antibiotics. Osteomyelitis may heal after long-term treatment with antibiotics (several months) or by surgically removing the infected bone tissue. The formation of abscesses is often treated by drainage and deep wound revision. In complicated cases, major or minor amputation is required. Signs of diabetic angiopathy should lead to assessment for vascular surgery with the aim of finding indications and potential for revascularisation surgery. Neuropathic ulcers are often located at the arches and areas strained by harmful pressure. Reducing dynamic foot pressure is a well-established form of therapy, and non-removable pressure-offloading walkers ensure better healing than removable ones. Applying a total contact cast is a specialist therapy. If there are signs of harmful pressure caused by abnormal bony prominences, orthopaedic surgery to correct inappropriate positioning or removing a bony prominence may be required. Foot ulcers are a heterogeneous condition in which comorbidity substantially influences the course of disease and the characteristics of the wound. It is therefore important to focus on treating other diseases associated with diabetic foot problems such as thrombophilia, generalised atherosclerosis and hypertension. In addition weak evidence supports positive outcomes for hyperbaric oxygen therapy, topical negative pressure therapy, and reconstructive methods for healing diabetic foot ulcers.

- How effective are telemedicine and multidisciplinary teams?

Telemedicine has the potential to profoundly affect the treatment of people with diabetic foot ulcers. Telemedicine directly influences wound treatment and the overall organisation and economics of the treatment of people with diabetic foot ulcers. The modest literature found provided no evidence that telemedicine treatment is effective in improving wound healing or patient outcome generally. However, telemedicine has numerous patient related and organisational advantages. Multidisciplinary teams have been recommended in Denmark since 1994. Only weak evidence indicates that multidisciplinary teams provide better treatment for people with diabetic foot ulcers than treatment

organised in other ways, but the literature review indicates that using multidisciplinary teams may have numerous benefits for organisation and for users of services.

The analysis of technology shows that targeted randomised controlled clinical trials are sorely needed within several specific diagnostic and treatment technologies used for diabetic foot ulcers. The problem is that the results of this type of trial will not be available within the near future, and similarly, it is uncertain whether the trials will have enough subjects to provide strong evidence. The challenge is to establish national goals and strategies as soon as possible, and new roads must be travelled to achieve this. One possibility in addition to initiation of randomised controlled trials is consecutively registering the technologies used in each person's course of treatment. This would not only contribute to the quality of disease management but also to the basis for a prospective research model for describing the evidence base for technologies.

Patient

The analysis of the patient-related aspects answers the following questions.

- How do people with diabetic foot ulcers experience their symptoms, and how does this affect diagnosis and treatment?

Most people with diabetic foot ulcers initially experience their symptoms as being trivial, which often results in diagnosis and treatment being delayed. The data gathered indicate that people generally underestimate the severity of the disease, and most people think that adjusting diet, exercise and pharmaceuticals will solve the problem and that they will then be healthy. Although some people with diabetic foot ulcers have participated in education on diabetes, their attitudes toward the disease are diffuse, and they seem to have forgotten important messages on foot ulcers when the situation arises. People's knowledge is not mobilised and implemented in practice until the foot ulcers appear. This also mostly applies to the therapists, who despite feedback from the people with foot ulcers are not sufficiently aware of the severity of the symptoms and thereby contribute to delaying effective efforts. Increased information is therefore needed on diabetic foot ulcers and on prevention, diagnosis and treatment among the people with diabetes and among their therapists.

- What are the characteristics of people with diabetic foot ulcers, and what social and cultural resources do they have available in their surroundings?

Studies show that people with diabetic foot ulcers often have several diseases simultaneously and are socially marginalised, and the disease affects men more severely than women. Studies show that people with diabetic foot ulcers are socially isolated and have a relatively low educational level and low social and economic status, and these factors make them especially marginalised, limit their access to care and increase the risk of amputation. The cultural competencies and social resources of these people are already limited, and the disease contributes further to their vulnerable position, with loss of self-esteem and reduced quality of life in all areas of life. This means that they have difficulty in complying with instructions so that their wounds heal optimally and instead conduct their own pragmatic risk assessment in relation to social, economic and practical factors, with the risk of exacerbating the situation. Living with diabetic foot ulcers burdens not only the people with diabetes but also their family members and may lead to conflicts, anger and frustration in the family, which has to confront economic and social insecurity. The anger is often directed towards the therapists and the public authorities that are intended to help the people with diabetes but instead are experienced as opponents in the struggle for basic rights.

- What opportunities and barriers do people with diabetic foot ulcers experience in relation to achieving satisfactory diagnosis and treatment?

From the perspective of the people with foot ulcers, security and continuity, respectful communication, holistic thinking and carrying out their daily activities without unnecessary pathologising are important prerequisites for achieving satisfactory diagnosis and treatment. The transition from hospitalisation to the home and a lack of linkage between the clinical reality and the person's life conditions at home especially comprise a barrier for satisfactorily managing the disease. The patients do not tell therapists about their private lives, and therapists do not ask, because they do not know what to do with the information. Despite broad awareness that considering both aspects of treatment as a whole is appropriate, this is not implemented in practice. This therefore places unrealistic self-care demands on the people with diabetes, and they feel guilty and are reluctant to inform about their neglect of self-care. Trustful communication between the person with diabetes and the therapist is best achieved through continuity and a holistic approach, and many people with diabetes therefore prefer treatment at centres with multidisciplinary teams or home consultations through telemedicine. Finally, the people with diabetes want treatment that maximises consideration of their desire for a life as an active and dignified citisen with access to the labour market and to social interaction.

Organisation

The analysis of organisational aspects answers the following questions.

- How is the treatment of people with diabetic foot ulcers organised in Denmark?

The analysis shows that Denmark's five administrative regions organise the diagnosis and treatment of people with diabetic foot ulcers differently. All the administrative regions have a more or less developed formal model of organisation based on detection by general practitioners and home care. All administrative regions enable referral to hospitals. Nevertheless, although all the administrative regions have an organisational unit with specialised knowledge on foot ulcers, either at a wound centre or as a multidisciplinary team at a regional hospital, who is referred to these units and how many vary. Some administrative regions lack clear guidelines for assessment and referral pathways and the division of labour internally. Even where guidelines exist, not all health professionals at all levels are aware of them. Assessment and referral and the division of labour are therefore implemented ad hoc and based on personal networks and traditions. The structure depends strongly on personal contacts between knowledge workers (as fiery souls) across formal organisations.

- What barriers and opportunities can be identified in the current organisation of diagnosis and treatment?

The analysis describes several specific problems related to the current organisation of diagnosis and treatment. There are especially problems related to general practice and the municipalities' role in detection and follow-up care as well as varying and unclear referral practices between primary and secondary health care and internally between hospitals. The heterogeneous organisation of hospital treatment across the five administrative regions is not an inherent problem, but given the unclear assessment and referral pathways and division of labour, uniformly applying specific organisational principles may provide improvement. A special challenge is a lack of good electronic communication tools that cover all actors in the health care system and that the opportunities for systematic monitoring through nationwide data on the quality of care and the like are lacking.

- What specific proposals for future initiatives can be identified with the aim of achieving appropriate organisation of diagnosis and treatment?

The question on future organisational practice was answered through literature studies and by assessing the statements of the focus groups on practical barriers and opportunities. Unfortunately, few systematic and generalisable studies on organisational factors related to the treatment of diabetic foot ulcers have been performed. An important recommendation for future initiatives is therefore to improve the opportunities in several areas for systematically gathering knowledge on various topics related to organisation. Nevertheless, based on the analysis, several initiatives are recommended that would probably strengthen the management of people with diabetic foot ulcers in the Danish health care system.

The main proposal is to develop national clinical guidelines and regional disease management programmes for diabetic foot ulcers. The analysis indicates the need to strengthen the organisational model within the administrative regions to ensure more uniform practice with a sufficiently high level of expertise in managing diabetic foot ulcers and to create appropriate work procedures, good communication with the rest of the treatment system and more uniform assessment and referral of the people with diabetes. For example, creating a more specialised regional unit than basic function that ensures rapid and qualified diagnosis and treatment of the most severe cases can strengthen the organisation of diagnosis and treatment. Further, the administrative regions should ensure that multidisciplinary teams are implemented at all levels. The multidisciplinary teams can be organised in different ways and can be anchored at different types of units. They should at least include relevant specialist physicians, specialist nurses and podiatrists with access to a clinic. Efforts should be made to produce improved knowledge on which types of teams function best under specific conditions.

The collaboration between the various therapists is a core problem with the current organisational model. The assessment and referral practices and communication on the services offered across administrative levels should be strengthened. The development of national clinical guidelines and regional disease management programmes for diabetic foot ulcers can contribute to bolstering this field. Another important prerequisite for strengthening collaboration is developing electronic communication systems that cover all relevant therapists. In connection with this, practices in information management need to be developed to facilitate the rapid and precise exchange of information.

Detection and follow-up care are important organisational prerequisites for creating good disease management programmes. General practitioners play an important role in both phases, but the analysis illustrates that they have very diverse approaches. It is very important to create good conditions for general practitioners to take the role of case manager for the health care system. The means to achieve this include developing better communication tools and practice in relation to the other parts of the health care system and continuing to improve information, professional support and the competencies of general practitioners.

Finally, better opportunities are needed to monitor the quality of the individual parts of the treatment chain in collaboration between the various professionals and units. Developing existing databases on the quality of care and bolstering the reporting to these databases are important factors in this process.

Economy

The analysis of economic aspects answers the following questions.

- What are the economic costs to society of diagnosing and treating people with diabetic foot ulcers?

A study in Sweden by Apelqvist et al. was used as a basis for the costs per person. They estimated the cost of treating people with diabetic foot ulcers that heal to be DKK 152,800-252,800 (€20,500-33,900) and the costs of treating people with diabetic foot ulcers that require amputation to be DKK 407,900-597,300 (€54,800-80,200). These estimates include the costs of treating any new foot ulcers these people get afterwards. The incidence of people treated for diabetic foot ulcers in Denmark was 3173 in 2006 and 3010 in 2009. For 2006, data are available for the distribution of the degree of treatment; among the people treated for diabetic foot ulcers, 9.7 % required minor amputation during the next 3 years and 13.2 % major amputation. Based on this, the annual cost of treating people with diabetic foot ulcers in Denmark in 2006 is estimated to be DKK 793 million (€106 million) in 2009 prices. The costs for home help are the largest portion of this at about 44 %, inpatient treatment 36 % and outpatient treatment 20 %. These are minimum estimates for the actual costs, since only the costs for the first 3 years after the foot ulcers are detected are included. Further, the loss of income of the person with the foot ulcers is not included.

- Which factors will determine the economic costs to society and the effects on operating costs of the various proposals for changing the organisation of diagnosis and treatment of people with diabetic foot ulcers?

The chapter on the organisation of diagnosis and treatment outlines several proposals for changing how the diagnosis and treatment of people with diabetic foot ulcers are organised in Denmark. The expected costs if the proposals are implemented could not be calculated, but the chapter indicates several factors that are expected to influence the magnitude of the economic effects. The costs associated with implementing the individual proposals are generally assessed to be modest, especially if the work of existing personnel, such as hospital personnel, is organised in new ways and they collaborate in multidisciplinary teams. Implementing telemedicine, however, will require investment in equipment and other items in accordance with the outcome of a project on wound treatment at Sønderjylland Hospital. Nevertheless, the proposals may have great indirect economic effects in the form of changing the volume of services provided by general practitioners and hospitals. It is thus decisive to ensure that the costs of any increased service activity lead to improved treatment outcome, such as declining probability of severe complications caused by foot ulcers. It is correspondingly important in implementing specific activities to focus on ensuring that Denmark's diagnosis-related group (DRG) system of reimbursement provides hospitals with the appropriate incentives and reimbursement for increased service activity.

Overall assessment

Diabetic foot ulcers result from the late complications of diabetes, especially diabetes-related neuropathy and angiopathy. Parallel to the development of these late complications, many people with diabetes develop diseases related to the circulatory system such as heart disease, brain injury and kidney disease. People who have had diabetes for many years often have diabetic foot ulcers together with other chronic diseases.

Studies show that people with diabetic foot ulcers comprise a heterogeneous group but have an excess of older men and the disease impairs their physical, emotional and soci-

etal functioning. People with diabetic foot ulcers often experience depression and lower quality of life and self-esteem. Studies show that people with diabetic foot ulcers often are socially isolated, and have a relatively low educational level and low social and economic status, and these factors make them especially marginalised, create difficulty in obtaining access to care and increase the risk of amputation. In addition, diabetic foot ulcers inherently contribute to limiting people's mobility and promoting social isolation. Living with diabetic foot ulcers burdens not only the people who have them but also their family members and can lead to conflicts, anger and frustration in families.

People with diabetic foot ulcers face the challenge of simultaneously managing the underlying disease, diabetic foot ulcers and the frequent co morbid chronic diseases. This is a great challenge, since the demands placed on the people with diabetic foot ulcers in connection with treatment are often extensive and potentially contradictory. The literature shows that the people with diabetic foot ulcers do not take the ulcers seriously enough in the early phase and are therefore surprised by the severity of the diabetic foot ulcers. The knowledge of the people with diabetic foot ulcers is not mobilised and put into practice until the ulcers actually appear. This also largely applies to the therapists who, despite being consulted by the people with diabetic foot ulcers, are not sufficiently aware of the severity of the symptoms and thereby contribute to delaying diagnosis and treatment. Preparing people with diabetes for the risk of developing foot ulcers and making them realise the seriousness of the foot ulcers at an early stage are important educational tasks. People with diabetic foot ulcers must obtain a realistic understanding of the disease based on knowledge so that they can contribute actively to achieving optimal results from treatment.

Studies outside Denmark show that the annual incidence of diabetic foot ulcers (the percentage of people with diabetes who have new foot ulcers within a 1-year period) among people with diabetes is 2-6 %, with a 5-year remission rate of 70 %. The prevalence of diabetic foot ulcers (the percentage of people with diabetes who have foot ulcers at any given time) varies in various studies in Scandinavia from 3 % to 10 %.

Data from the Danish National Patient Registry and the Danish National Diabetes Registry show that the number of new cases of diabetic foot ulcers was 3010 in 2009, and the total number of people with diabetes who had foot ulcers was 22,195 (including all degrees of severity). In 2008, 1.2 % of the people with diabetes developed foot ulcers for the first time (incidence), and 8.7 % of all people with diabetes had diabetic foot ulcers (prevalence). The prevalence in Denmark is thereby similar to the prevalence in other Scandinavian countries. The number of people with severe diabetic foot ulcers was 3984 in 2008, equivalent to 1.6 % of the people with diabetes. The calculations include only people with diabetes who were treated in a hospital; the people treated in general practice are not included because of limitations in registration. This means that the figures are underestimated and do not include people who complete treatment in general practice, which especially indicates foot ulcers that are not severe.

Three factors limit the prerequisites for organising the diagnosis and treatment of people with diabetic foot ulcers more appropriately. First, the literature review of the outcomes of the various technologies used for diagnosing and treating people with diabetic foot ulcers shows that the evidence base is poor. Many technologies have no or a limited evidence base on outcome, and few technologies have an evidence base that is moderate in quality (blood testing, bone scintigraphy, magnetic resonance (MR) scanning, peripheral blood pressure monitoring using a strain-gauge technique, Seldinger technique for angiography, relieving harmful pressure with a total contact cast and revascu-

larisation) and moderate to good (biothesiometry testing, monofilament testing and improving cardiovascular risk factors). Most of the technologies require further study. The lack of evidence on the outcomes of the technologies does not necessarily mean that they are not effective, but this presents challenges in providing guidance on the appropriate organisation of diagnosis and treatment since well-documented technologies are needed for organising diagnosis and treatment. Second, research has not adequately investigated the outcomes of the initiatives to improve the organisation of diagnosis and treatment proposed in the report, and assessing the precise effectiveness of these initiatives is therefore difficult. Third, the lack of evidence on the outcomes of the technologies and the limited knowledge on the outcomes of the initiatives to improve the organisation of diagnosis and treatment prevented analysis of the cost-effectiveness of the organisational initiatives, which could have supported setting priorities among the initiatives.

Despite these conditions, this report indicates several options for appropriately organising the diagnosis and treatment of diabetic foot ulcers. The considerations that follow are especially based on the analysis of the current organisational model and its weaknesses and analysis of interviews that provide the basis for describing possible future organisational initiatives. Nevertheless, knowledge of the needs of patients in relation to organisation and the need to ensure the positive development of evidence on the outcomes of the technologies support and extend the conclusions of this analysis. An important prerequisite for improving diagnosis and treatment is to create the framework and conditions needed to produce evidence on diagnosis and treatment that can lead to progress in the future.

Analysis of the existing organisational model shows that this field is organised very heterogeneously, and the organisation of diagnosis and treatment seems to generally lack coherence in many places. This is demonstrated by the diversity of guidelines, criteria for assessment and referral and the use of technologies in this field. Further, various types of hospital departments carry out diagnosis and treatment in different parts of Denmark. This is not inherently problematic but may still pose challenges in a field that severely lacks evidence on technologies and in which rapid access to very broad multidisciplinary expertise is decisive. Further, existing disease management programmes seldom incorporate diagnosis and treatment for diabetic foot ulcers. National clinical guidelines have not been prepared, local guidelines are lacking in several local areas and health professionals in other local areas are not familiar with the existing guidelines, and the organisation in this field therefore needs to be improved. Preparing national clinical guidelines and then incorporating diabetic foot ulcers into the disease management programmes for diabetes may appropriately support this improvement. This will ensure appropriate links between the existing evidence related to the technologies in this field and the future organisation of diagnosis and treatment. Looking forward, the quality of diagnosis and treatment should be monitored to ensure that the quality of everyday clinical practice complies with the professional standards established by the clinical guidelines. Further, systematic reporting to existing databases should be ensured.

The report indicates the need for creating a more specialised regional unit than basic function in each administrative region that can manage diagnosis and treatment related to the most complex and severe cases of disease. This regional unit should have access to all the necessary competencies incorporated into multidisciplinary teams but can be organised in different ways. For example, all competencies could be gathered geographically in the unit, so that the specialist physicians can consult the people with diabetic

foot ulcers at the same time or very close in time. Alternatively, the competencies could be gathered in looser networks (perhaps in several geographical locations) with easy access for the people with diabetic foot ulcers and good communication across the team. Nevertheless, this last method requires clear agreements on when the various medical specialties are to be involved in diagnosis and treatment. Careful consideration should be given to how many hospital departments in each administrative region are involved in treating people with diabetic foot ulcers. The analysis of the needs of the people with diabetic foot ulcers supports increasing specialisation or more clearly focusing the organisation of the medical specialties in the administrative regions. The current complex organisational model places immense demands on the ability of the people with diabetic foot ulcers to take responsibility for treatment programmes in which they must potentially interact with and initiate contact with many health professionals. Since the people with diabetic foot ulcers have great co morbidity and are socially marginalised, many are challenged in taking responsibility for their own treatment programme, and their need for simpler treatment programmes should be carefully integrated into the future organisational model.

The report similarly shows great variation in the criteria for assessment and referral across the administrative regions. The stage at which the people with diabetic foot ulcers are referred from primary health care to secondary health care differs vastly. The chapter on technology emphasises the importance of diagnosing infection immediately, but the literature review also shows that making this diagnosis is difficult. This may indicate that general practitioners should refer the people with diabetic foot ulcers exceeding grade 0 on the Wagner Classification of Diabetic Foot Ulcers to a regional unit for assessment by specialist physicians. Such an organisational model may be combined with referring the people with diabetic foot ulcers to more local treatment if the foot ulcers can easily be treated in the diabetes clinics or in general practice, perhaps supplemented by home care, to avoid burdening the capacity of the regional service unit unnecessarily. In this connection, strict criteria should be established to govern when patients should be referred again to the regional unit if the foot ulcer does not heal. At a minimum, the time when the people with diabetic foot ulcers should be referred to secondary health care and to which unit or units they should be referred need to be more precisely clarified. Further, it should specifically be clarified who has authority to refer people with diabetic foot ulcers to secondary health care, since home nurses may already refer people with diabetic foot ulcers in some places. If such schemes are established, it is important that the people who obtain the authority to carry out referral have the necessary competencies to carry this out.

The analysis shows that the role of general practice similarly needs to be strengthened in this field. The familiarity of general practitioners with diabetic foot ulcers varies, as does their carrying out the role as a case manager. Their role is made more difficult by the fact that they currently have few people with diabetic foot ulcers in their practice. The rarity of diabetic foot ulcers combined with the recognition that severe diabetic foot ulcers may be difficult to diagnose mean that the people with diabetic foot ulcers should be ensured easy and immediate access to centres with multidisciplinary expertise within diagnosis and treatment. The analysis of the organisation of diagnosis and treatment also indicates that developing general practice into larger units may create the potential for general practitioners to carry out more tasks in the diagnosis and treatment of people with diabetic foot ulcers. Conversely, structuring the organisation of this field in the short term requires considering the current state of general practice. Geographical conditions may influence the role of general practitioners, since people with diabetic foot ulcers who live far from hospitals may be more likely to avoid follow-

up treatment in hospitals. These people with diabetic foot ulcers should be ensured optimal conditions; one way to do this is to use telemedicine for follow-up treatment.

The diagnosis and treatment in hospitals should be organised based on multidisciplinary teams from now on. The course of disease is complicated for many people with diabetic foot ulcers since many health professions and medical specialties are involved. Weak evidence indicates that organising diagnosis and treatment in multidisciplinary teams directly improves the outcome for people with diabetic foot ulcers, but ensuring a structured framework for involving the necessary competencies would obviously strengthen the organisational model. No research supports any conclusions on which health professions or medical specialties should be incorporated into multidisciplinary teams or how this should be organised. Nevertheless, the analysis of organisation indicates that at least the following health professions and medical specialties should be included: physicians (endocrinology, orthopaedic surgery and vascular surgery), nurses specialising in diabetes and wound care and podiatrists with access to a work shop. Further, people with diabetic foot ulcers should have easy access to physical therapy, plastic surgery, radiology, orthopaedic technicians and orthopaedic shoemakers and perhaps to specialist physicians in relation to new and more advanced treatment. Further, there should be clear agreements and structures related to collaboration and exchange of information with other health professionals consulted by the people with diabetic foot ulcers, especially general practitioners, home care professionals and podiatrists in private practice.

Finally, telemedicine is a technology that is expected to play a greater role in the future organisation of diagnosis and treatment. Telemedicine is considered a good tool for ongoing follow-up after people with diabetic foot ulcers have been referred and have been diagnosed and treated at a hospital. This technology can also play an important role for the people with diabetic foot ulcers who live far from a hospital. Various methods are used such as still images and live images, and no research has indicated any preference for one method over another. Nevertheless, experience from the administrative regions that have begun to use telemedicine indicates that transmitting live images with the opportunity for simultaneous communication with social and health care assistants and home nurses is preferable. Knowledge is generally lacking on the clinical and organisational outcomes of using telemedicine, on cost-effectiveness and on the organisational prerequisites needed to attain optimal benefits from telemedicine. A mini-health technology assessment by the Region of Southern Denmark found positive results for both treatment and economics, but the Region initiated a more detailed study in October 2010 investigating the clinical, organisational and economic outcomes. Considerable money is currently being invested in telemedicine, and investing some of this money in investigating these outcomes is appropriate. One barrier for using telemedicine could be that Denmark has not yet established DRG reimbursement rates for telemedicine services in relation to diabetic foot ulcers.

In addition to the proposals for initiatives already mentioned that can contribute to a more appropriate organisational model, improved collaboration, communication and information exchange between health professionals are needed. People with diabetic foot ulcers especially want security, continuity, communication and holistic approaches in the course of diagnosis and treatment. Having a case manager for the disease treatment programmes is considered very important. Communication is an immense challenge across sectors but also across both the clinical reality and the reality of the people with diabetic foot ulcers, including knowledge on understanding the conditions of their daily lives. Systematic efforts are required to ensure appropriate and rapid

exchange of information between all actors, including the publicly employed health professionals and health professionals in private practice (such as podiatrists).

The health professions managing people with diabetic foot ulcers in both primary and secondary health care need to be ensured the necessary training and information, including knowledge on such topics as guidelines, just as responsibilities need to be clearly delegated to ensure appropriate diagnosis and treatment.

The proposals mentioned above are expected to contribute constructively to promoting and formalising collaboration, communication and information exchange, but ongoing attention needs to be focused on these factors, since the organisational model is extremely complex and is decisive for the people with diabetic foot ulcers to experience high quality in the treatment programme.

No studies of the costs of diagnosing and treating people with diabetic foot ulcers in both primary and secondary health care had previously been conducted in Denmark. The total annual economic costs to society of diagnosing and treating the people with diabetic foot ulcers in Denmark are an estimated DKK 793 million (€106 million). Costs for home help are the largest portion of this at about 44 %, hospitalisation 36 % and outpatient treatment 20 %. These are minimum estimates for the actual costs, since only the costs for the first 3 years after the ulcer is detected are included. Further, the loss of income of the person with the foot ulcers is not included. The considerable costs associated with diagnosing and treating the people with diabetic foot ulcers continue to require great focus on the organisational model in this field, since appropriate organisation is expected to lead to earlier diagnosis and improved treatment.

Guidance

Based on this report, the following recommendations can be disseminated to key health care actors in the state, administrative regions and municipalities.

- Active efforts should be made to integrate the daily lives of the people with diabetes into the organisation of diagnosis and treatment in partnership with the people with diabetes.
- National clinical guidelines should be prepared that are intersectoral and include relevant medical specialities and health professions.
- The existing disease management programmes for diabetes should incorporate prevention, diagnosis, treatment and follow-up care for foot ulcers.
- The quality of diagnosis and treatment should be monitored to ensure that the quality of everyday clinical practice complies with the established standards. Systematic reporting should be ensured to existing registries and databases in this field, such as the National Indicator Project and the data capture module of the Danish Quality Unit of General Practice (DAK-E).
- Efforts should be made to move towards adopting a uniform classification of diabetic foot ulcers that can be used in both primary and secondary health care to ensure an identical basis for comparison across hospitals and health sectors. The Wagner Classification of Diabetic Foot Ulcers is one possible choice, since this has already been implemented in numerous contexts. The University of Texas Diabetic Wound Classification System is another instrument.
- Establishing a more specialised regional unit than basic that ensures rapid and qualified diagnosis and treatment of the most severe cases function in each administrative region should be considered

- To be able to diagnose and treat infection, neuropathy, angiopathy and harmful pressure on the foot the following services should be available and easy to access for the patients:
  - diagnostic imaging, at least including conventional X-rays and magnetic resonance (MR) scanning;
  - diagnosis of infection – ensuring access to laboratories for blood tests etc.;
  - ability to diagnose angiopathy, at least including peripheral blood pressure measurement using the strain-gauge technique, assessment by a vascular surgeon and angiography;
  - local wound treatment, including wound revision;
  - surgery to correct harmful pressure on the foot;
  - revascularisation surgery;
  - pharmaceutical and surgical treatment for infection;
  - relieving harmful pressure, including access to a podiatrist's workshop and pressure-relieving aids;
  - amputation;
  - reconstructive methods; and
  - diagnosis and treatment for important co morbid diseases.

- In addition to these functions, the regional unit should be able to refer to more advanced diagnostic imaging techniques, plastic surgery, hyperbaric oxygen therapy and topical negative pressure therapy.
- Clear and more uniform guidelines should be prepared for assessing and referring people with diabetic foot ulcers to diagnosis and treatment from primary health care to secondary health care and internally within secondary health care.
- General practice should be strengthened in the following ways.
  - The role of general practice as case managers:
    General practitioners have a key role in the lives of people with limited social, mental and physical resources. Knowledge of these people's conditions and co morbidity may contribute to identifying and reducing barriers to timely and optimal treatment. This task is time-consuming and requires good intersectoral communication.
  - The proactive efforts of general practice:
    General practitioners have an important educational role in making the people with diabetes realise the severity of the foot ulcer at an early stage and contributing to ensuring that they achieve a realistic understanding of the disease. This requires that general practitioners be well informed about the other therapists involved and about the assessment and intervention of each health profession.
  - The professional role of general practice:
    To carry out tasks in relation to detecting, diagnosing and treating diabetic foot ulcers, the quality of professional services provided by general practitioners can be improved through close contact with specialist physicians, including easy access to telephone consultation, and through telemedicine and training personnel.
- The future organisation of diagnosis and treatment should be based on multidisciplinary teams that at least include physicians (endocrinology, orthopaedic surgery and vascular surgery), nurses specialising in diabetes and wound care and podiatrists with access to a workshop. Further, people with diabetic foot ulcers should have easy access to physical therapy, plastic surgery, radiology, orthopaedic technicians and orthopaedic shoemakers and perhaps to specialist physicians in relation to new and more advanced treatment.

- The use of telemedicine in following up the treatment for diabetic foot ulcers should be developed under controlled conditions that enable the advantages and disadvantages of this method to be evaluated.

Research should include the following fields.

- Regional centres for diagnosis and treatment of people with diabetic foot ulcers should collaborate, and this should enable randomised controlled multicentre trials to be carried out with the aim of finding evidence on the outcomes of the technologies used for diagnosis and treatment.
- Evidence is lacking on the outcomes of various alternative methods of organising diagnosis and treatment in Denmark. Special efforts should be made to obtain evidence on the optimal methods of organising multidisciplinary units and telemedicine and of implementing guidelines.
- More research is needed on the outcomes of the proposed changes in organisation, and more knowledge is needed on the clinical outcomes and the economic costs to society associated with the changes. Nevertheless, the lack of knowledge should be viewed based on the fact that research on the quantitative effects of organisational change is difficult in practice. The reason is that implementing a change in organisation, such as introducing multidisciplinary teams, often influences how all personnel carry out their tasks, which thereby creates difficulty in offering samples of subjects under both the old and new organisational models in a randomised trial in the same hospital department. These practical difficulties, however, should not hinder more research on these interventions, since knowledge in this field is decisive for improving future wound treatment.
- Knowledge is lacking on the attitudes of people with diabetes towards the diabetes generally and towards foot ulcers specifically. Organising effective efforts to inform and treat people with diabetes requires conducting qualitative studies that investigate people's own experience of and attitudes toward the situation.
- Knowledge is lacking on the quality of life of patients in the form of quantitative data. The potential to link registries and measuring instruments such as quality-adjusted life-years, the SF-12 Health Survey, self-rated health, measurements of social outcomes, health profiles and other instruments should be investigated.

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