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Development and validation of a pocket guide for the prevention of diabetic foot ulcers

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Abstract

Objective: Diabetic foot ulcers can have serious consequences, including amputation. This project aimed to develop and validate a diabetes care management model—a pocket guide on the prevention of foot ulceration to assist health professionals and scientific societies.

Methods: An adaptation of the Iowa method of evidence-based practice to promote high-quality care was employed. After problems are identified, the Iowa method supports the development of an action plan for addressing them. An evidence-based protocol based on the five cornerstones of the 2015 guidance on the diabetic foot by the International Working Group on the Diabetic Foot was developed in two phases and validated using the Delphi technique.

Results: A model was developed to promote these five cornerstones, which are the main recommendations for managing the diabetic foot. These are: foot examination; risk assessment for ulceration; education in diabetes; appropriate footwear; and treatment of pre-ulcerative lesions. To adapt this into a health information document, the management model was synthesised and

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designed as a pocket guide. The model's individual and global content validity indices surpass 0.78 and 0.90 respectively.

Conclusion: A management model was created and validated, and produced as a pocket guide to deliver instructions on the care and prevention of diabetic foot problems in people with diabetes.

Keywords

Diabetes; Diabetic foot; Patient care management; Clinical management; Evidence-based practice; Nursing

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The prevalence of diabetes has reached concerning levels worldwide, particularly in developing countries. According to the latest data released by the International Diabetes Federation (IDF) (2019), 463 million people across the globe are affected by diabetes, which corresponds to 9.3% of the global population.

About 26 million people with diabetes develop foot ulcers annually (Bakker et al, 2015; International Working Group on the Diabetic Foot (IWGDF), 2019). Medical expenses for people who have both diabetes and ulcers are five times higher than for those who have diabetes but no ulcer (IDF, 2017a). Moreover, ulcers may lead to amputation, an outcome 20 times more common in people with diabetes than in people without diabetes (IDF, 2017b). Among all amputations associated with foot ulcers, diabetic foot ulcers lead to up to 83% of major amputations and 96% of minor amputations (World Union of Wound Healing Societies, 2016). In addition, patients who have amputations related to diabetic foot ulcers have extremely high mortality rates, with up to 70% dying within 5 years (Bakker et al, 2015).

Another cause of concern is diabetic foot ulcer recurrence. Approximately 40% of patients have ulcer recurrence within 1 year of being cured, 60% within 3 years, and 65% within 5 years. This has led researchers in this area to opt for the concept of ulcer remission rather than cure (Armstrong and Mills, 2013; Armstrong et al, 2017).

Given this, there is an urgent need for structured services and up-to-date guidelines in the management of people with diabetes, which should include care for the lower extremities, as they are the site of complications that may lead to severe negative outcomes, such as ulceration and amputation (Frykberg et al, 2006; Wu et al, 2006).

Most ulcerations that could potentially lead to amputation result from factors such as pre-ulcerative lesions (also called non-ulcerative lesions), trauma from inappropriate footwear and minor traumas such as that resulting from walking barefoot (given the diabetic foot's lack of plantar sensitivity). Such factors can be avoided through educational and preventive programmes, as well as foot care and monitoring (Bakker et al, 2015). Foot care management by a structured, interdisciplinary team can reduce the number of amputations by up to 80% (IDF, 2019).

The Delphi technique allows for group consensus to be reached on a topic, through consultations with people who are considered experts in a field. This adds credibility to the validated content, as it has been filtered by renowned professionals. After agreeing

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to participate in the process, these experts are referred to as judges. Judges are consulted via questionnaires sent to each participant over the same period (Mancussi e Faro, 1997). Judges do not have access to each other's responses, which minimises the likelihood of them influencing each other. In general, a numerical value within a Likert-type scale is assigned to each question. Judges can also provide written opinions (Spínola 1984; Mancussi e Faro, 1997).

There is no ideal number of participating judges. Expert selection depends on the object of interest and the comprehensiveness of a judge's knowledge in the target area.

In addition to having extensive knowledge on the subject matter, the expert should be willing to participate in all stages of the process. It is important that examination of the questionnaires by the judges and their return to the group's administrator should take place according to pre-established deadlines (Spínola, 1984).

There is no fixed number of rounds of consultation. Generally, two or three rounds are sufficient to get a group consensus on the topic. Too many rounds discourage expert participation, which makes it difficult to analyse the data and delays the study's conclusion (Castro and Rezende, 2009).

The Delphi method was used to validate the contents of the pocket guide, with the collaboration of Brazilian experts in the area of diabetes and the diabetic foot. This final product—an educational guide on the prevention of foot complications in people with diabetes—represents the opinion of several experts, not just one.

In this study, it was proposed to draw up, validate and design a pocket guide to disseminate a diabetes care management model. This model focuses on early screening, risk classification and the prevention of foot complications. These clinical activities are routinely provided at the Speciality Centre of Diabetes at the Federal University of São Paulo (Unifesp), and in other regional centres. The guide is also supported by the five cornerstones of the IWGDF (Bakker et al, 2015).

Method

This study is based on evidence-based nursing practice and takes a methodological approach. The development and validation of the management model complies with the principles of the International Diabetic Foot Consensus, drawn up by the IWGDF, and has stages of construction according to the Iowa model, as adapted by Titler et al (2001). The Iowa method has several sequential, interdependent steps. The elaboration and validation of the management model was performed according to the principles of the IWGDF.

This entailed several stages of construction, in line with the Iowa model (Polit and Beck, 2006). The Iowa method for the implementation of evidence-based practice comprises several sequential and interdependent steps.

The first step is the identification of a problem within an institution; the second examines whether the identified problem is relevant and should be considered a priority. If so, a

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team is formed and the available research on the subject is assembled. If the research base is sufficient, preparation for practice changes are started. Otherwise, the research work is extended or support from other types of evidence, such as case reports and expert opinions, is sought.

Next, evidence-based guidelines are developed and a pilot practice change with defined goals is implemented. The pilot's results are then evaluated and, if the change is considered appropriate, it is implemented definitively, with monitoring and analysis of data on its structure, process and results.

In this study, the quality-assessment method for the inclusion of care practices examined the accuracy of these practices as secondary care interventions, considering diabetes-related lower-extremity diseases.

The organisation of this management model was based on the IWGDF's five cornerstones (Box 1) (Bakker et al, 2015). These were formulated according to the best evidence and scientific recommendations.

The construction, pilot implementation and validation of the diabetes management model for the prevention of lower extremity ulcerations was carried out in two phases, which were divided into several sequential and interdependent steps.

Initially, a set of problems in the institution was selected as a target (late diagnosis, and a high number of ulcerations and amputations in people with diabetes). A search was then performed of the Descritores em Ciência da Saúde (Descriptors in Health Science; DeCS) online database to identify the relevant descriptors and their corresponding items in the Medical Subject Headings (MeSH) database. Finally, a search using the descriptors identified was carried out in the main medical databases.

The search for references did not provide strong enough evidence on which to base the protocol, so it was necessary to include publications with less strong evidence, such as case reports and expert opinions.

One of the steps in the Iowa method is to implement a pilot project. This pilot was carried out after formal authorisation by Unifesp's specialist diabetes centre and the university's ethics committee. The 77 patients included in the pilot were enrolled in the centre, having been referred to it by the diabetic neuropathy department. Patients with bilateral transtibial amputation were excluded from the study, as well as those unable to attend consultations (according to risk classification). Patients were informed about the nature of the research, as well as its purpose and relevance. After giving verbal agreement, they were invited to give written informed consent.

The patient-evaluation instrument used was developed by Pedrosa et al (2014). The clinic room was adapted, with structural and architectural adjustments and the installation of equipment that the project was expected to need.

The pilot included the assessment and physical examination of the feet, classification of the risk of developing foot ulceration, education for self-care, guidance or referral regarding

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footwear, and treatment of pre-ulcerative signs and of ulcers. These were followed up depending on their ulcer risk score.

The Delphi technique and the content validity index (CVI) were chosen to validate the management model.

Validation of the information on foot care had three stages. In the first, feedback was gathered from the judges on content and layout. At this stage, all suggestions were carefully considered, and a number of these were deemed pertinent.

The incorporation of these suggestions gave rise to the first version of the pocket guide. This was then sent to the judges again with a return deadline. Once all the evaluations had been received, these were analysed. By this stage, the guide had been validated by the majority of experts.

A further round of adjustments gave rise to the second version of the pocket guide, which was, once again, sent to experts. Each expert said whether this second version was ‘approved’ or ‘not approved’ by them.

After the experts had reached a consensus, content validation was applied to the guide’s contents. The scales most commonly used in content validation are the Likert, Thurstone and Guttman (Castro and Rezende, 2009).

Likert scales allow participants to respond to a question or statement by allocating a score. For example, they can choose between five scores: strongly agree (5); agree (4); neither agree nor disagree (3); disagree (2); and strongly disagree (1). A Likert scale was adopted in this study. Besides allowing each expert’s individual opinion on the subject to be measured, the Likert can also be used to assess the level of agreement among all judges. To measure the individual opinion of each expert, the following calculation was adopted (Alexandre and Coluci, 2011).

$$\text{CVI} = \frac{\text{Number of ‘4’ or ‘5’ responses}}{\text{Total number of questions}}$$

A 70% concordance between experts usually indicates a general consensus (Mancussi e Faro, 1997; de Almeida et al, 2009). However, in this study, a minimum agreement of 90% was established as a parameter for general consensus, with 78% for consensus on individual items (Polit and Beck, 2006).

To collect data on the first two steps of the validation process, a questionnaire with two parts, based on a previous piece of work (Sousa and Turrini, 2012), was designed.

The first part concerned the judges’ demographic details, academic backgrounds and clinical experience. The second concerned to the evaluation of the content regarding: graphic presentation; ease of reading and comprehension; logical sequence; vocabulary; topicality; specific physical examination of the lower limbs; risk classification; education for patients

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in self-care; education of health professionals (regarding the use of adequate footwear and pressure relief); and, finally, therapy adopted for the treatment of non-ulcerative pathologies.

The second part involved an the adaptation of the previous questionnaire, but without a Likert scale. The questionnaire content was divided into the five cornerstones. Accepted suggestions were added to each, and justifications made for those that were not accepted. A field with the choice to approve or not approve the guide's final version was also included, together with a justification field to be filled in case of a negative answer.

The judges were well-known diabetes experts who were invited and agreed to participate in the study. The snowball strategy was used to select these professionals. After a professional was appointed, the Lattes platform (a Brazilian government scientific information system that includes researchers and institutions) was consulted so the appointee's curriculum could be evaluated and approved. When the inclusion criteria (Box 2) had been met and a minimum of five points scored, the specialist was contacted through an invitation letter sent via email. Those who agreed to participate in the survey were invited to sign the informed consent term and access the online questionnaire in Google Docs.

Deadlines for completing the questionnaires were set. Two judges were excluded from the study: one did not participate in the second stage, and another did not participate in the third stage of the validation process. The final sample had 11 experts.

Results

During the management model validation process, 11 specialists provided the data necessary to generate the individual and global CVIs.

Table 1 shows the calculation of the CVI for each item of the model and of the final document. This calculation was based on the methodology of Alexandre and Coluci (2011), who state that CVI is the total of 'agree' and 'strongly agree' answers divided by the number of judges giving those answers—ie the proportion of 'approved' answers within the total number of answers given by the judges.

The management model had satisfactory CVIs (Polit and Beck, 2006), with all individual items reaching values above 0.780 and the overall model surpassing 0.900 (Table 1).

While analysing the study's data, statistical tests were applied to the data generated by the 11 specialists' assessments of each of the five cornerstones of the IWGDF's diabetes care management model for the prevention of lower extremity ulceration (Box 1) (Bakker et al, 2015). Each specialist rated the cornerstones of the model by as 'approved' or 'not approved'. Five response sets from each of the 11 specialists were analysed, totalling 55 responses.

Table 2 shows the responses to each cornerstone of the model by each evaluator. The 'approved' and 'not approved' responses are coded as 1 and 0 respectively. This numerical coding was used to calculate the intraclass correlation coefficients, as explained below.

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Table 3 presents the CVI calculation for each management model cornerstone and for the management model as a whole. This calculation was based on the methodology of Alexandre and Coluci (2011), who described the CVI as the proportion of 'approved' answers within the total number of answers given by the judges. The results in Table 3 demonstrate that the management model had satisfactory CVIs (Polit and Beck, 2006), with all individual items reaching values above 0.780 and the overall model surpassing 0.900. The second result refers to the improvement and adjustment of the initial protocol, which was formatted as a pocket guide (Figure 1).

Discussion

A foot care management model based on topical evidence and the best scientific recommendations—in the format of a pocket guide—may support decision-making and health interventions targeting foot care in people with diabetes. Its organisation according to cornerstones indicates actions that have to be carried out by health professionals to fulfil the assessments and interventions required.

The Delphi technique was used to validate the guide's content with the help of experts in the area of diabetes and the diabetic foot. This validated educational material clarifies the IWGDF five cornerstones, stimulating their application in order to prevent foot complications in people with diabetes.

The development of an evidence-based management model enables health professionals to guide diabetes care while emphasising that foot care is worthwhile. It is important to note a guide alone does not guarantee that actions to support health will be implemented. However, developed countries that use protocols and algorithms to improve risk assessment rates and results indicator scores recommend manuals, guides and algorithms as strategies for careful, systematic evaluation of procedures in specialist areas (Bakker et al, 2015; IDF, 2019; National Institute for Health and Care Excellence (NICE), 2019; Sociedade Brasileira de Diabetes (SBD), 2020).

According to the IWGDF, a programme for the prevention of foot complications must begin with a system to identify all people at risk of ulceration. This should be done through annual monitoring. Additionally, structured services should be established for the management of patients who require care for chronic rather than acute conditions. Screening people at risk of ulceration and classifying their risk is the most important aspect of a system to prevent foot complications and amputations in people with diabetes (Pham et al, 2000; Boulton et al, 2008; Miller et al, 2014; Bakker et al, 2015; Boulton et al, 2018).

People with diabetes should have their feet examined annually to identify if they have a low, moderate or high risk of ulceration. Patients who already have some type of foot alteration should be screened more frequently (NICE, 2019). The first and second cornerstones concern identifying feet at risk, with a goal of classifying risk. Risk should be categorised by scores in a range of 0–3, where 0 is the lowest and 3 the highest risk of developing a foot ulcer (Bakker et al, 2015; NICE, 2019). Once classified, patients needto be

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followed up according to the intervals required so they receive interventions to prevent foot complications depending on the risk factors identified (SBD, 2020).

The third cornerstone concerns education for the person with diabetes, family members, caregivers and health professionals—an essential part of nursing care. The education of patients with diabetes and their families is fundamental to the prevention of foot complications, and includes self-monitoring glucose and the correct use of insulin and other medications, regular foot care and hygiene, wearing footwear that is appropriate, immediate notification of foot ulceration to the responsible health professional, and regular follow-up with a podiatrist for nail and skin hygiene (Frykberg et al, 2006).

Health education has several advantages and does not overlap with other clinical activity. Indeed, it strengthens clinical adherence and encourages self-care. It must be in accordance with the individual conditions of each person, and respect their individuality and reality. There should be a shared responsibility for healthcare and multidisciplinary solutions should be sought, such as self-monitoring, foot care, shoe adaptation and mobility. The integration of these principles can not only guide the use of dressings but also strengthen other therapeutic resources, such as patient-professional communication, enhancing the effects of health education and replacing care that is centred on the disease with person-centred care (Gamba et al, 2014).

People with diabetes need to make several changes to their lifestyle; only by acquiring knowledge of their condition will they be able to exert control over it. One of the main goals of education in the many aspects of diabetes is to improve outcomes by providing access to information and ensuring that patients understand it. Education in diabetes is not only part of its treatment but also a fundamental condition for the organisation and management of care (Gamba et al, 2014).

The fourth cornerstone concerns the use of footwear designed to redistribute plantar pressure. Inappropriate footwear is one of the main problems leading to foot ulceration in people with diabetes (Bakker, 2014). The prescription of comfortable or customised footwear is widely indicated to aid in pressure redistribution and the prevention of ulcerations (Bus et al, 2011). However, this type of prescription is little known in healthcare practice, and a guide recommending this measure may be of great importance in the context of primary health care (van Netten et al, 2018).

It is important to note that such recommendations should consider each patient’s specific needs, as there is no one-size-fits-all shoe for diabetic patients. The shoe recommendation has to be directly related to neurological, circulatory and musculoskeletal changes identified. Regular, specialist or customized footwear should be recommended depending on the risks identified (Schaper et al, 2016). People with diabetes who are at a low risk of ulceration may use regular footwear that fits their foot correctly to minimise the risk of injury; those at moderate risk should use footwear with features designed to meet the needs of people with diabetes; and those at high risk should wear customised shoes and insoles (Bergin et al, 2013). Therefore, it is essential for health professionals to understand the importance of inspecting the patient’s footwear. Practitioners must evaluate their patients’ feet and, if

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a high risk of ulceration is identified, should advise the patient of the most appropriate footwear, which can be readymade or customised.

The fifth cornerstone concerns the treatment of non-ulcerative lesions. These are generally associated with calluses, fissures, onychocryptosis, mycosis affecting the skin and nails, onychogryphosis and blisters. Pre-ulcerative lesions in the feet of people with diabetes are predictive of more severe complications such as ulcerations, infections and even amputation.

Several authors have discussed the importance of the prevention and early treatment of these lesions. Most studies and guidelines (Frykberg et al, 2006; Bakker et al, 2015; SBD, 2020) recommend including a podiatrist in the multidisciplinary care team. This already happens in the USA and Europe. In countries where this professional is not part of the team, such as Brazil (which does not yet have public policies that include the involvement of this practitioner), it is advisable for a nurse to be trained to assume this role (Secretaria de Estado de Saúde do Distrito Federal, 2001). Here in Brazil, the SBD recommends that nurses trained or who specialise in clinical podiatry care for the feet of people with diabetes (SBD, 2020).

This pocket guide will be distributed to nurses through a partnership with the Brazilian Society of Nursing in Stomatherapy (whose members are wound, ostomy and continence nurses), through which nurses can access the website and download the a copy of it.

Regarding nurse training, it is planned that diabetes, stomatherapy and dermatology societies will contribute to public and private undergraduate education. The pocket guide can provide a great support to these professionals to encourage the care of feet in the management of people with diabetes.

The authors hope that people with diabetes, health professionals, patient associations, and scientific and civil societies will benefit from this guide, using it as a source of health information to improve the care and quality of life of thousands of people with the condition. It is hoped it will contribute to a reduction in diabetes-related amputations, as envisioned by determined researchers and experts in the area.

Conclusion

A diabetes foot care management model based on evidence and the best scientific recommendations was developed and validated. The model is based around five cornerstones on the management of pre-ulcerative lesions.

Although guidelines on this subject are widely disseminated, it is still necessary to improve the skills of the professionals who provide this care.

The pocket guide model was validated by Brazilian experts in the area of diabetes and the diabetic foot, reaching a global content validity index above 90% which means a high standard of score. **BJN**

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Box 1.

Five cornerstones for the prevention of lower extremity ulceration used in the guide

Key elements of diabetic foot care

- Regular inspection and examination of the at-risk foot
- Identification of the at-risk foot
- Education of the patient, the family and healthcare providers
- Appropriate footwear
- Treatment of non-ulcerative pathology

Source: Bakker et al, 2015

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Box 2.

Criteria for selecting expert participants for the validation process

Work in area of interest	Score
Thesis or dissertation	2 points per work
Graduation or specialist monograph	1 point per work
Participation in groups or projects	1 point
Teaching experience	0.5 point per year
Professional practice	0.5 point per year
Adviser on work	0.5 point per work
Authorship of two works, published in periodicals	0.25 point per work
Participant in examination boards	0.25 point per work

Source: Teles et al, 2014

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KEY POINTS

- Foot ulceration in people with diabetes can lead to amputation and high health costs
- Regular inspection and examination of at-risk feet can prevent secondary complications of diabetes
- Health education is an essential part of diabetes care
- Ensuring the diabetic person has the type of footwear best suited to their needs is crucial
- Treatment of pre-ulcerative lesions on the feet is a can prevent severe complications in people with diabetes
- A validated pocket guide can be a useful tool to improve how health professionals prevent and manage foot ulcers

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CPD reflective questions

- How could health professionals be encouraged to examine the feet of people with diabetes and assess their risk of foot ulceration?
- How could patients be encouraged to care for their feet?
- What should be considered for a simple pocket guide to provide an algorithm for diabetes healthcare?

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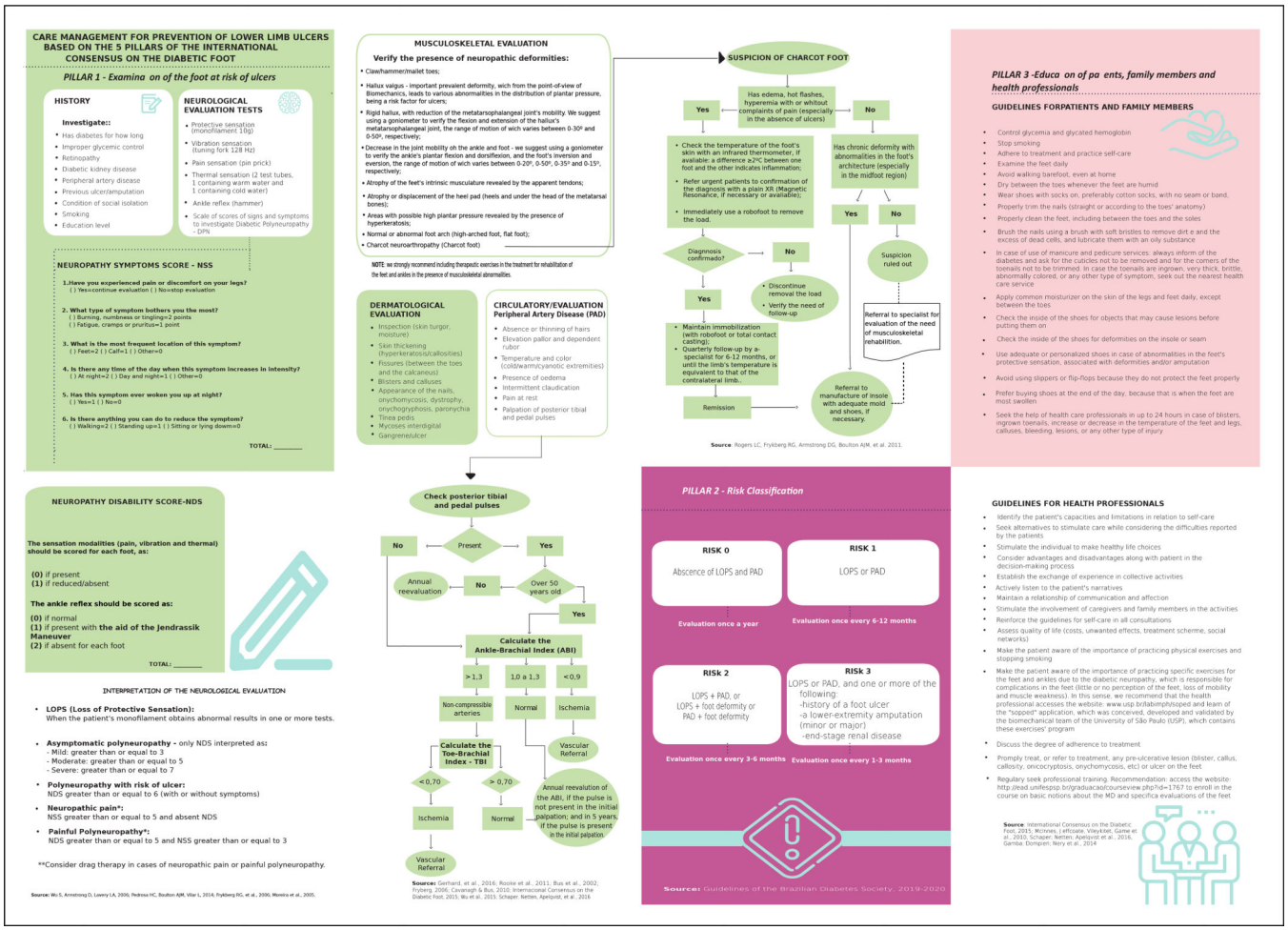

Figure 1a.
The pocket guide, unfolded, side 1

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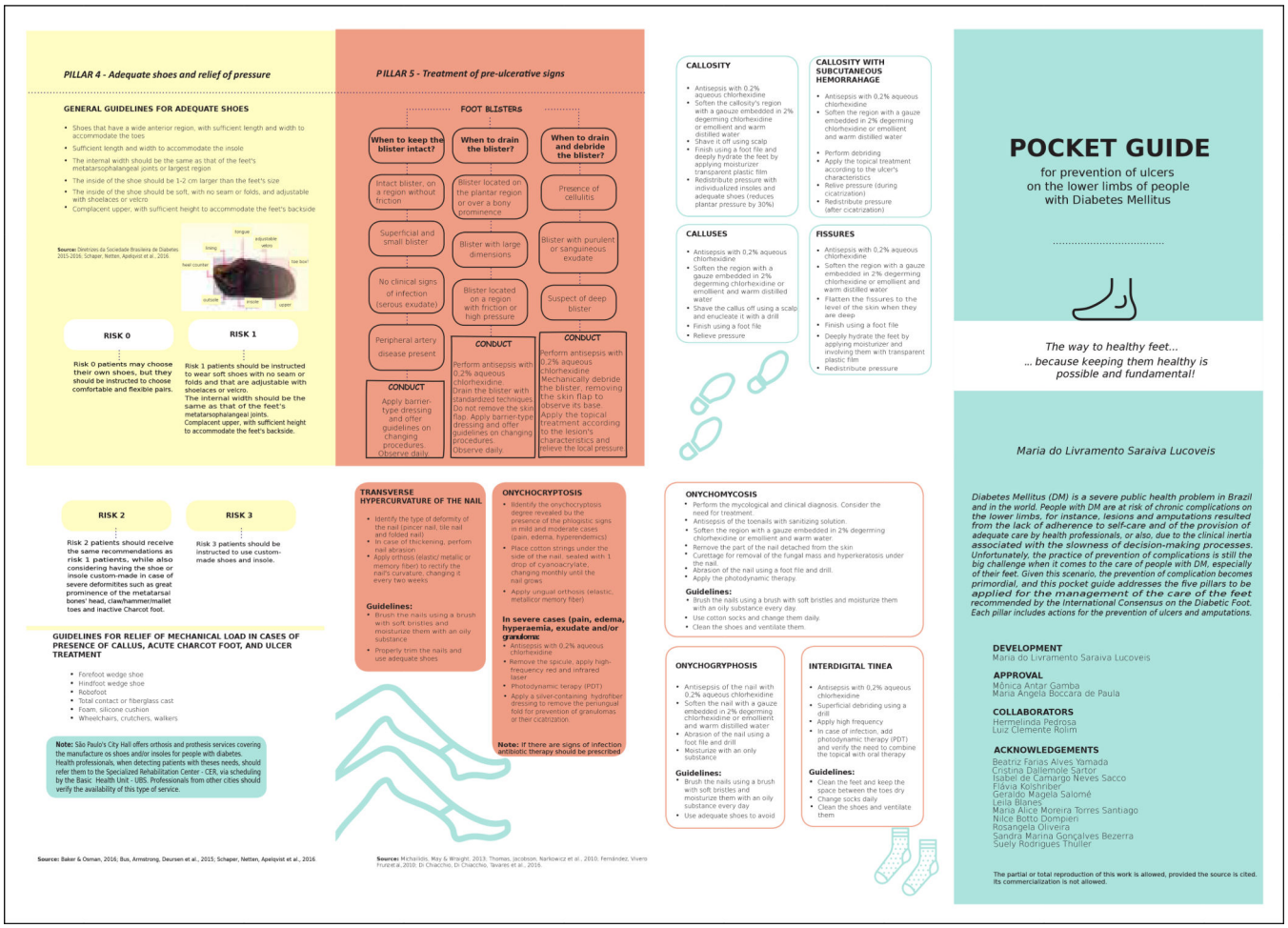

Figure 1b.
The pocket guide, unfolded, side 2

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Table 1.

Management model content validity index: total and individual item scores

Item index	Content validity	Item	Content validity index
Final model	**0.908**	2.10	0.917
2.1	1.00	2.11	0.833
2.2	0.917	2.12	0.833
2.3	1.00	2.13	0.833
2.4	1.00	2.14	0.917
2.5	0.833	2.15	0.917
2.6	0.833	2.16	0.917
2.7	0.917	2.17	0.917
2.8	0.917	2.18	0.917
2.9	0.917	2.19	0.917

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Table 2.

Specialists' agreement with the management model's cornerstones

Model cornerstones	Specialist										
	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	A11
1	1	1	1	1	1	1	1	1	1	1	1
2	1	1	1	1	1	0	1	1	1	1	1
3	1	1	1	1	1	1	1	1	1	1	1
4	1	1	1	1	1	1	1	1	1	1	1
5	0	1	1	1	1	1	1	1	1	1	1

0: not approved; 1: approved

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Table 3.

Content validity index of the management model as a whole and for each cornerstone

Item	Content validity index
Full model	0.964
1	1.000
2	0.909
3	1.000
4	0.909
5	1.000