Antibiotic prescription using a digital decision support system: a register-based study of patients with hard-to-heal ulcers in Sweden

Hanna Linnea Wickström, Cecilia Fagerström, Rut Frank Öien, Peter Anderberg, Patrik Midlöv

Objective To investigate differences in antibiotic prescription for patients with hard-to-heal ulcers assessed using a digital decision support system (DDSS) compared with those assessed without using a DDSS. A further aim was to examine predictors for antibiotic prescription.

Design Register-based study.

Setting In 2018–2019, healthcare staff in primary, community and specialist care in Sweden tested a DDSS that offers a mobile application for data and photograph transfer to a platform for multidisciplinary consultation and automatic transmission of data to the Registry of Ulcer Treatment (RUT). Register-based data from patients assessed and diagnosed using the DDSS combined with the RUT was compared with register-based data from patients whose assessments were merely registered in the RUT.

Participants A total of 117 patients assessed using the DDSS combined with the RUT (the study group) were compared with 1784 patients whose assessments were registered in the RUT without using the DDSS (the control group).

Primary and secondary outcome measures The differences in antibiotic prescription were analysed using the Pearson’s χ² test. A logistic regression analysis was used to check for influencing factors on antibiotic prescription.

Results Patients assessed using a DDSS in combination with the RUT had significantly lower antibiotic prescription than patients entered in the RUT without using the DDSS (8% vs 26%) (p=0.002) (only healed ulcers included). Predictors for antibiotic prescription were diabetes; long healing time; having an arterial, neuropathic or malignant ulcer.

Conclusions A DDSS with data and photograph transfer that enables multidisciplinary communication appears to be a suitable tool to reduce antibiotic prescription for patients with hard-to-heal ulcers.

Introduction Hard-to-heal ulcers, usually leg ulcers, mainly affect elderly and multidiseased patients. The underlying cause of the ulcer, that is, the aetiological diagnosis, must be found and treated to achieve healing. Examples of hard-to-heal ulcers are venous, arterial or venous-arterial leg ulcers; diabetic foot ulcers; pressure ulcers and ulcers due to trauma, rheumatoid arthritis, inflammation and malignancy. It is estimated that 1% of the population in the industrialised world will experience a hard-to-heal ulcer during their lifetime.

Wound management in Sweden is carried out in primary or community care in close collaboration with hospital specialist clinics such as dermatology, vascular, endocrinology, infection and orthopaedic clinics. A multidisciplinary team of staff is often needed to establish ulcer aetiology, provide a diagnosis and develop treatment strategies. Well-functioning arrangements for collaboration between primary, community and specialist care are thus crucial for ulcer healing. This collaboration in healthcare may be achieved using modern technical solutions, such as a digital decision support system (DDSS), to support medical decisions and secure communication.

A DDSS is defined as an information system intended to help healthcare workers in making medical decisions, diagnosing, prescribing or prognosticating in a safe and
quality-assured way,⁷ DDSSs are expected to assist collaboration within and across organisational boundaries in healthcare.⁵ DDSSs can take several forms, such as mobile applications or web browser platforms for consultations, automatic answers or discussion forums with or without photograph transfer.

eHealth with photograph transfer is used within wound management in Europe, resulting in reduced waiting time,⁹ ulcer healing time¹⁰ and patient transportation.⁹¹⁰ Real-time video consultations have been shown to contribute to reduced waiting and healing time,¹¹ and are also suitable for assessing ulcer pain and prescribing analgesics for patients with hard-to-heal ulcers.¹²

The Swedish national quality registry of hard-to-heal ulcers (the Registry of Ulcer Treatment, RUT)¹³ has contributed to the development of a DDSS for wound management in collaboration with a technology company. The DDSS is designed to be used when a nurse or assistant nurse meets a patient for dressing changes. It can be used as a tool to collect and transfer data to a platform where medical information and photographs can be shared within wound healing teams for multidisciplinary consultation. It also automatically transmits mandatory data to the RUT, which is used by primary, community and specialist care in Sweden, and currently has more than 10 000 registered ulcers.¹³ The RUT is free to use and offers, with its validated manuals, a structured ulcer care. Detailed information about registering in the RUT and the mandatory variables may be found elsewhere.¹³¹⁴

One complication in wound management is ulcer infection. Treatment-seeking infection in hard-to-heal ulcers varies from 8% to 27%¹⁵–¹⁸ in earlier publications, depending on the ulcer aetiology and the underlying diseases of the patient. For diabetic foot ulcers, the presence of treatment-seeking infection is more frequent compared with the whole group of hard-to-heal ulcers. An earlier study has shown that 58% of diabetic foot ulcers were infected,¹⁹ why this patient group must more often be treated with antibiotics by specialised multidisciplinary teams. In practice, antibiotics are prescribed incorrectly and much more often than necessary to patients with hard-to-heal ulcers.¹⁴¹⁷¹⁹ This increases the general burden of antibiotic resistance and impacts the patient’s well-being due to medical interactions and side effects. In Sweden, it is not unusual for physicians to prescribe antibiotics without assessing the patient themselves; it is done as a corridor consultation or by a telephone call from a nurse. It is crucial that clinicians prescribe antibiotics wisely, taking into account that the majority of hard-to-heal ulcers are colonised by bacteria and that an antibiotic is only required when the ulcer is clinically infected²¹ and where debridement and local antiseptics (non-antibiotics) are not sufficient.²¹²² Improperly prescribed antibiotics might delay the correct treatment, with prolonged ulcer healing time as a consequence. Studies have shown that continuity of care, doctor–patient relations and treatment by a specialised team all impact the antibiotic prescription pattern.¹⁴²³ Deficiencies in the structural care of patients with hard-to-heal ulcers, such as treating the patient without proper aetiological diagnosis by a physician and lack of continuity, are common in Sweden.¹⁴

eHealth solutions have been used for infection assessment and prescription of antibiotics, with contradictory outcomes. For instance, a study in the USA showed increased rates of antibiotic prescription for acute bronchitis when consultations were made by telemedicine compared with inperson consultation.²⁴ Other studies have shown that eHealth solutions could decrease and advise on antibiotic prescribing when used as a tool offering caregivers educational support.²⁵²⁶ However, there is a lack of research about how antibiotic prescribing is affected when eHealth solutions such as a DDSS are used for patients with hard-to-heal ulcers. We need to find out whether a DDSS with ability to guide assessments and facilitate sharing medical information and photographs of ulcers between caregivers, could affect prescribing of antibiotics for patients with hard-to-heal ulcers.

The aim of this study was to compare register-based data on antibiotic prescription for patients assessed using a DDSS with patients where a DDSS was not used. A further aim was to examine predictors for antibiotic prescription.

METHODS
Design
This is a register-based study where data automatically transferred from the DDSS to the RUT are compared with data entered in the registry without using the DDSS.

Study population
All patients with hard-to-heal ulcers registered in the RUT between 1 January 2018 and 31 December 2019 were included in this study. In the RUT, a hard-to-heal ulcer is defined as a break in the skin that has not healed within 6 weeks.¹³ Of the registered patients, a total of 117 patients were registered in the RUT using the DDSS (study group) and 1784 patients were registered directly in the RUT without using the DDSS (control group).

Patient and public involvement
Patients or the public were not involved in the design, or conduct, or reporting of the study.

Setting
Registering in the RUT
Patients are registered in the RUT according to standardised and validated manuals by a nurse, assistant nurse or physician on two occasions. The first registration includes variables such as age, gender, diabetes, smoking habits, ulcer size, ulcer duration, ulcer pain and ankle-brachial pressure index, and also the specific aetiological diagnosis. The second registration includes data on ulcer healing, antibiotic treatment or negative clinical events such as amputation or death. Each patient remains in the registry until the second registration is completed.

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Registrations are done during or after a consultation with a nurse, assistant nurse or physician. Registrations take place in primary, community and specialist care at different registering units in Sweden, with wide geographical spread. The RUT has 272 connected care units (out of 1390 units treating patients with hard-to-heal ulcers in Sweden). Specified information about the registrars is not available in this study.

Using the DDSS
Sixty-five healthcare staff volunteered to test the DDSS in their local wound management team over a 6-month test period in 2018–2019. Use of the DDSS was free. The participants were physicians, nurses and assistant nurses across Sweden who were frequently treating patients with hard-to-heal ulcers and also registering them in the RUT. They worked in both urban and rural areas, and they all received the same information and technical support. The recruitment was done during an annual user meeting for registrars. Specified information about the participants who tested the DDSS is not available in this study.

The DDSS consists of a mobile application for bedside assessment that automatically transmits data to the RUT and to a web browser platform for multidisciplinary consultation (see figure 1). The treating staff obtain the patient’s consent to use the DDSS and to transmit data to the RUT. Thereafter, they collect and fill in the mandatory variables (the same as in the RUT) in the mobile application and take photographs of the ulcer and the used dressing material. The collected variables and photographs from the mobile application are then transmitted to the web browser platform, and the variables are transmitted simultaneously to the RUT. The physician or the tissue viability nurse in the wound management team receives an alert by email that a new patient case is waiting on the web browser platform. They can then make a medical assessment by providing an aetiological diagnosis, treatment strategy and prescription for antibiotics if needed. This information is communicated in writing on the platform. The wound management team can invite external consultants to the platform if specific professions are required. The availability of external consultants depends on whom the team has chosen to work with, which could be a dermatology clinic, vascular clinic or any other type of clinic. Information about the use or lack of use of external consultation with other clinics, how frequently this was done and which clinics are not available in this study.

The DDSS is designed to delete all data from the mobile device following transmission to the web browser platform and to the RUT, in accordance with security rules. The DDSS is CE certified according to Medical Devices Class I (D3.0–112015) and compliant with healthcare regulations and the General Data Protection Regulation. The difference between using the DDSS and not using the DDSS is that the DDSS offers a digital platform where the wound management team can assess the ulcer together by reading/analysing the information (collected variables), looking at photographs, consulting and communicating digitally concerning the patient.

Figure 1 The digital decision support system (DDSS) (figure by Gnosco AB, www.dermicus.com).
In this study age (years), gender (female/male), having diabetes (yes/no), smoking (yes/no), ulcer size (cm²), ulcer duration (days), registered by using the DDSS or not (yes/no) and aetiological diagnosis (see below) were collected from the first registration in the RUT. Follow-up data (healed, not healed, deceased, amputated, disrupted registration for other reasons), ulcer healing time (days) and prescription of antibiotics (yes/no) were collected from the second registration in the RUT. Information about the prescription of antibiotics (yes/no) during the healing time is only available if the ulcer is registered at follow-up as healed. The specific type of antibiotic that was prescribed is not registered in the RUT.

Ulcers were categorised by aetiological diagnosis through clinical assessment according to the RUT as venous ulcers, arterial ulcers, venous-arterial ulcers, pressure ulcers, neuropathic ulcers (mostly diabetic foot ulcers), traumatic ulcers, malignant ulcers (mostly ulcerated basal cell carcinoma or cutaneous squamous cell carcinoma), ulcers due to inflammatory vessel diseases such as vasculitis and other unspecified ulcers.

Ulcer healing time was defined as the interval between registration in the RUT and complete ulcer healing. A healed ulcer was defined as an ulcer covered by epithelial regeneration, beneath which there may be scarring and an absence of glands or appendages.

### Data analysis

Statistical analysis was performed using V.25 of IBM SPSS Statistics. Normally distributed variables were expressed as mean values and SD, and compared using the Student’s t-test. Non-normally distributed variables were expressed as median values and ranges, and differences between groups were analysed using the Mann-Whitney U test. Differences in healing time between groups were analysed using a log-rank test. Categorical variables were compared between groups using Pearson’s χ² test. The relationship between receiving antibiotic prescription and all the variables from the first registration in the RUT as well as healing time from the second registration was investigated in a bivariate correlation analysis presented with the Spearman’s rank correlation coefficient, Spearman’s rho (r). Variables significantly associated with antibiotic prescription in the bivariate analysis were then entered into logistic regression analysis (Enter), in addition to gender and age. As a reference, younger age, male, not having diabetes, shorter healing time, not using the DDSS, and not having the specific ulcer aetiology were chosen. The regression coefficient expresses the independent contribution of potential determinants to antibiotic prescription. To determine if the regression model provided a good fit to the data, both the Hosmer and Lemeshow test and the Nagelkerke test were performed. A p value of less than 0.05 was considered to indicate statistical significance.

### RESULTS

#### Patient demographics

A total of 1901 patients were registered in the RUT during the study period, of which 117 were registered using the DDSS (the study group) and 1784 were registered in the RUT without using the DDSS (the control group).

Basic data are presented in table 1. The study group had a mean age of 77 years (SD 13), the median ulcer size was 6 cm² (min–max 0.1–442 cm²) and the median ulcer duration was 16 weeks (min–max 1–371 weeks). The control group had a mean age of 75 years (SD 14), the median ulcer size was 3.8 cm² (min–max 0.01–400 cm²) and the median ulcer duration was 12 weeks (min–max 0–2008 weeks). There were no significant differences in age, gender, having diabetes or smoking habits between the groups. The study group had significantly larger ulcers and longer ulcer duration than the control group.

There were differences in the distribution of ulcer aetiologies between the groups (p<0.001). The most prominent difference was the larger proportion of arterial ulcers in the study group compared with the control group. The aetiology of the ulcers in each group is presented in table 2.

### Table 1 Patient demographics

<table>
<thead>
<tr>
<th></th>
<th>Study group n=117</th>
<th>Control group n=1784</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)*</td>
<td>77 years (13)</td>
<td>75 years (14)</td>
<td>0.071</td>
</tr>
<tr>
<td>Female, percent†</td>
<td>59</td>
<td>54</td>
<td>0.257</td>
</tr>
<tr>
<td>Having diabetes, percent†</td>
<td>33</td>
<td>32</td>
<td>0.689</td>
</tr>
<tr>
<td>Smoking, percent‡</td>
<td>9</td>
<td>12</td>
<td>0.322</td>
</tr>
<tr>
<td>Ulcer size, median (range)‡</td>
<td>6.0 cm² (0.01–442)</td>
<td>3.8 cm² (0.01–400)</td>
<td>0.018</td>
</tr>
<tr>
<td>Ulcer duration, median (range)‡</td>
<td>16 weeks (1–371)</td>
<td>12 weeks (0–2008)</td>
<td>0.001</td>
</tr>
<tr>
<td>Healing time, median (95% CI)§¶</td>
<td>49 days (31 to 67)</td>
<td>70 days (64 to 76)</td>
<td>0.012</td>
</tr>
</tbody>
</table>

Significant p-values are presented in bold.

*Student’s t-test.
†χ² test.
‡Mann-Whitney U test.
§Log-rank test.
¶Only analysed on healed ulcers.

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The percentage of healed ulcers was in total 57% (1080 out of 1901); 55% (64 patients) in the study group and 57% (1016 patients) in the control group. In the study group, 18% had not been registered as healed, 13% had deceased, 13% had disrupted registration for other reasons, and 1% had been amputated. In the control group, 26% had not been registered as healed, 6% had deceased, 10% had disrupted registration for other reasons and 1% had been amputated. Arterial ulcers were the predominant aetiological diagnosis among deceased patients in the study group, and pressure ulcers followed by arterial ulcers predominated as the aetiological diagnosis among deceased patients in the control group.

The median healing time of all healed ulcers was 69 days (95% CI 63 to 75). The median healing time was 49 days in the study group and 70 days in the control group (p=0.012; table 1). In the study group, 86% of the healed ulcers had a healing time of less than 6 months and 14% healed within 6–12 months. In the control group, 84% of the healed ulcers had a healing time of less than 6 months, 13% healed within 6–12 months, and 3% had a healing time >12 months.

**Antibiotic prescription during healing time**

There was a significant difference in antibiotic prescription between the study group and the control group during the healing time (only healed ulcers included) (p=0.002). In the study group (n=64), 8% (n=5) of the patients received antibiotics (86% (n=55) received no antibiotics, 6% (n=4) had no data registered concerning antibiotic prescription). In the control group (n=1016), 26% (n=263) received antibiotics (71% (n=724) received no antibiotics and 3% (n=29) had no data registered concerning antibiotic prescription).

Arterial ulcers, neuropathic ulcers, ulcers due to inflammatory vessel disease, and malignant ulcers had the highest proportion of prescribed antibiotics (50%, 53%, 43% and 54%, respectively) when analysing all healed ulcers in the study group and the control group together.

Venous ulcers, venous-arterial ulcers, pressure ulcers and traumatic ulcers (20%, 15%, 17% and 23%, respectively) had the lowest proportion of prescribed antibiotics. Patients with other unspecified ulcers received antibiotic prescriptions in 37% of cases, compared with 22% of those missing aetiological diagnosis. The antibiotic prescription in specific aetiological diagnoses could not be compared between the study group and the control group, as the frequencies were too low. Table 3 shows the proportion of antibiotic prescriptions in different aetiological diagnoses in the study group and the control group separately, for all healed ulcers.

In a bivariate analysis of all healed ulcers, a significant correlation was found between antibiotic prescription and diabetes (Spearman’s rho, r=0.121, p<0.001); healing time (r=0.197, p<0.001); registered using the DDSS (r=0.098, p=0.002); venous (r=0.090, p=0.005); arterial (r=0.129, p<0.001); pressure (r=0.089, p=0.005); neuropathic (r=0.121, p<0.001); malignant (r=0.075, p=0.020); and other unspecified ulcers (r=0.101, p=0.002).

Logistic regression analysis showed that having diabetes (OR, 1.718, p=0.003), longer healing time (OR 1.004, p<0.001), having an arterial ulcer (OR 3.005, p=0.001), having a neuropathic ulcer (OR 3.855, p=0.002), having a malignant ulcer (OR 4.016, p=0.018), not using the DDSS (OR 0.283, p=0.012) or not having a pressure ulcer (OR 0.542, p=0.031) were predictors for antibiotic prescription (see table 4). Logistic regression analysis separately for the two consultation groups did not add any further information due to the small numbers in the study group.

**DISCUSSION**

The main finding in this study was a significant difference in antibiotic prescription during healing time between the
study group (8%) and the control group (26%). Predictors for antibiotic prescription were diabetes; longer healing time; having an arterial, neuropathic or malignant ulcer; and not using the DDSS. Another finding was a significantly shorter healing time in the study group compared with the control group. The findings of reduced antibiotic prescribing and shorter ulcer healing time imply that the use of a DDSS that enables multidisciplinary consultation can improve wound management.

Antibiotic prescription was found to be significantly lower when using the DDSS compared with not using the DDSS in wound management, which is in line with earlier studies showing less antibiotic prescription when using eHealth tools such as decision support systems. Reduced prescription may, in turn, contribute to reducing the general health burden of antibiotic resistance. The proportion of antibiotic prescription seen in both groups in this study was in agreement with earlier studies of infection in hard-to-heal ulcers, supposing neither under-prescription nor overprescription. The lower proportion of antibiotic prescription seen when using the DDSS could be due to the fact that patients in the study group had significantly shorter healing time than the patients in the control group. The regression analysis, however, showed an independent influence of using the DDSS on antibiotic prescription. One explanation of this result may be the fact that the prescriber (eg, the physician) had access to photographs and had an opportunity to communicate and obtain additional information about the ulcer in the DDSS, making it easier to assess signs of infection and make a correct decision about antibiotic prescription. In this study, it is not known whether the prescriber for the patients in the control group actually assessed the ulcer before prescribing antibiotics, as it is not uncommon to prescribe antibiotics without clinical examination, for example, by telephone. Lack of staff continuity and demands from patients or other staff are also known to affect a physician’s prescription of antibiotics. Cooperating and consulting in digital wound management teams using the DDSS, including getting input from different staff working with continuity around the patient, may also contribute to the difference in antibiotic prescription between the study group and control group. These explanations are in line with earlier results describing the usefulness of DDSSs to make medical decisions, and to enable collaboration around the patients with hard-to-heal ulcers. To sum up, multidisciplinary collaboration has been proven to be a successful concept for wound management, and the DDSS contributes to such collaboration, with the additional benefit that the patient can be treated at home, not obliged to travel, even when different clinics and professionals are involved.

When studying antibiotic prescription in different aetiologies separately, we found that the groups were too small to draw conclusions regarding the impact of the DDSS on antibiotic prescription. Yet, there was a general movement towards a lower proportion of antibiotic prescriptions in all different ulcer aetiologies in the study group compared with the control group. Two aetiological diagnoses showed a higher proportion of antibiotic prescription in both groups, namely arterial and neuropathic ulcers. None of the pressure ulcers in the study group were prescribed antibiotics, compared with 18% in the control group. There are no recent or larger publications regarding the prevalence of infection in pressure ulcers. The only found article reported the incidence of infection to be 1.4 per 1000 ulcer days. Antibiotic prescription for traumatic ulcers clearly differed between the study group and control group, with a lesser proportion of prescription seen when the DDSS was used. Patients missing aetiological diagnosis had antibiotics prescribed in a reasonable proportion, but less when the DDSS was used. The group of other unspecified ulcers constitute rare aetiological diagnoses with completely different properties, making it hard to draw conclusions about this group. There is a need for larger studies focusing on specific aetiological diagnoses, and presence of infection and antibiotic prescription to be able to find out how eHealth might affect underprescription or over-prescription of antibiotics for different diagnoses.

The regression analysis of the whole group of healed ulcers, including both the study group and the control group, concluded that having diabetes independently predicted antibiotic prescription. This is in agreement with a position document from European Wound Management Association where diabetes is described as a risk factor for ulcer infection. The regression analysis also showed that arterial, neuropathic and malignant ulcers were predictors for receiving antibiotics. The

<table>
<thead>
<tr>
<th>Table 4 Logistic regression analysis for being prescribed antibiotics</th>
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<tbody>
<tr>
<td>Prescribed antibiotics (yes or no)</td>
</tr>
<tr>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Age 1.011</td>
</tr>
<tr>
<td>Gender 0.898</td>
</tr>
<tr>
<td>Diabetes 1.718</td>
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<tr>
<td>Healing time 1.004</td>
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<tr>
<td>Using the DDSS 0.283</td>
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<tr>
<td>Venous ulcer 0.835</td>
</tr>
<tr>
<td>Arterial ulcer 3.005</td>
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<tr>
<td>Pressure ulcer 0.542</td>
</tr>
<tr>
<td>Neuropathic ulcer 3.855</td>
</tr>
<tr>
<td>Malignant ulcer 4.016</td>
</tr>
<tr>
<td>Other unspecified ulcer 1.529</td>
</tr>
</tbody>
</table>

Outcome: Being prescribed antibiotics (yes). Younger age, male, not having diabetes, shorter healing time, not using the DDSS and not having the specific ulcer aetiology were chosen as references. Hosmer and Lemeshow’s goodness of fit p value was 0.320. Nagelkerke R² was 0.155. Significant p values are presented in bold.

DDSS, digital decision support system.
the presence of staphylococcus aureus, but its impact on neoplastic squamous cell carcinoma has shown increased antibiotic requirements. To authors' knowledge, the prevalence of patients with arterial ulcers receiving antibiotics, in accordance with findings that they constitute a risk group for infection. The fact that 54% of such patients in this study received antibiotics appears to be a high proportion, but further studies are needed. Biopsies of skin cancer (cutaneous squamous cell carcinoma) have shown increased presence of staphylococcus aureus, but its impact on antibiotic requirements remains unclear. In addition, an increased incidence of cutaneous squamous cell carcinoma can be seen in immunosuppressed patients, who are also more at risk of infection. To investigate prescribing patterns by analysing predictors and risk factors is important in order to direct efforts towards more adequate prescribing, since antibiotic resistance is a global threat. This study shows that predictors of antibiotic prescribing are linked to risk factors for ulcer infection and that a DDSS can affect antibiotic prescription.

Another predictor for being prescribed antibiotics was long healing time. The longer an ulcer stays unhealed, the longer the patient is at risk of antibiotic-requiring infection. This confirms how important it is for patients with hard-to-heal ulcers to receive accurate treatment as quickly as possible, in order to have the shortest possible healing time. The shorter healing time in the study group could not be explained by a preference for using the DDSS for the easiest ulcers, since the study group had longer ulcer duration, larger ulcer size and a higher proportion of arterial ulcers than the control group, indicating greater ulcer severity. The shorter healing time seems to be a result of the opportunity to collaborate in multidisciplinary teams by using the DDSS for optimal treatment. Reduction in healing time and in antibiotic prescription have both been explained by structured wound management based on accurate diagnosis, continuity of care, and follow-up to ulcer healing in an earlier register-based study of hard-to-heal ulcers. However, the higher proportion of deceased patients in the study group could be explained by a higher proportion of arterial ulcers compared with the control group. When examining the aetiological ulcer diagnosis of the deceased patients, arterial ulcers predominated. A recent study of mortality among patients with chronic ulcers reported that the mortality risk is the highest with arterial ulcers. However, the higher proportion of deceased patients in the study group does not necessarily mean that some deaths are linked to untreated infection cannot be ruled out. Further investigation is needed. Furthermore, a higher proportion of patients in the study group did not receive an aetiological diagnosis compared with the control group, which might be explained by the fact that the DDSS is used by staff for swift consultation, not for diagnosis. This constitutes a risk, since proper diagnosis is strongly linked to adequate treatment and hence ulcer healing.

Strengths and limitations

The RUT covers wound management in primary, community and specialist care in Sweden, and provides a reliable tool for diagnosis and follow-up. The large and representative sample of patients from the RUT implies that the result of the study is generalisable to patients with hard-to-heal ulcers. Another strength of the study is that the DDSS is used in parallel with and at the same time as the RUT, not in a single region but nationwide. The DDSS can thus be applied worldwide within all kinds of healthcare systems, although the absence of national quality registries in many countries may impact its full effectiveness. The combination of the DDSS with its sharing of information and photographs and a national registry not only ensures optimal treatment and care but also maps the situation for patients with hard-to-heal ulcers within an entire country. One limitation of the study is that staff selected the patients/ulcers for the study. Moreover, the staff themselves chose to sign up to use the DDSS, which probably means that this group was particularly interested in wound management. Furthermore, the current study group was compared with other patients with ulcers assessed by the RUT. An earlier register-based study has shown reduced antibiotic prescription after patients are registered in the RUT, compared with before registration. This finding was explained by the more structured care when using the quality registry. If the study group was to be compared with patients not registered in the RUT, the difference in antibiotic prescription might be even more pronounced. Another limitation of the study is that the antibiotic prescription is only analysed for those with documented healed ulcers during the study time. Register-based research is built on reported data from registrars who are not obliged to complete the follow-up registration; they are merely sent repeated reminders to do so in order to minimise missing data. It cannot be ruled out that missing data for antibiotic prescribing may affect our results, even if the amount of missing data is low in both the study group and the control group. The regression analysis does, however, take missing data into account, and shows low but acceptable goodness of fit to data. The low goodness of fit is probably explained by other unknown associated factors not emphasised in this study, owing to the limited number of variables in the RUT. Immunodeficiency diseases and immunosuppressive medications are among the unknown factors that need to be further investigated. The bivariate correlation analysis, performed to refine the regression model, showed significant correlations but with low to moderate
relationship/coefficients, which may be related to the sample size.

CONCLUSION

Antibiotic prescription for patients with hard-to-heal ulcers was lower when a DDSS was used compared with when it was not used. Diabetes, long healing time, having an arterial, neuropathic or malignant ulcer were predictors for antibiotic prescription.

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Contributors

The concept and design of the study were done by all authors; HLW, CF, RFö, PA and PM. Data analysis and the drafting of the initial manuscript were carried out by HLW. HLW is the author responsible for the overall content as guarantor. All authors provided critical revision of the paper and have read and approved the final submitted version.

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Competing interests

None declared.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication

Not applicable.

Ethics approval

This study involves human participants and was approved by the Ethical Review Board of Lund, Sweden (ref: 2018/209). Participants gave informed consent consistent with the principles of Swedish national quality registries to participate in the study before taking part.

Provenance and peer review

Not commissioned; externally peer reviewed.

Data availability statement

All data relevant to the study are included in the article or uploaded as online supplemental information.

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