

Specialised wound care clinics in Spain: distribution and characteristics

Objective: To determine the number of specialised wound care units/clinics (SWCUs) in Spain, at present, and to describe their most important characteristics.

Method: This was an observational study with a descriptive-analytical, cross-sectional, multicentre approach, where the studied population consisted of SWCUs in Spain. A specific data-collection questionnaire was designed using a modified Delphi method, consisting of four rounds, with the collaboration of 10 wound experts. The final questionnaire included 49 items distributed across four dimensions/areas with a content validity index (CVI-Total for pertinence=0.96 and CVI-Total for relevance=0.94).

Results: A total of 42 SWCUs were included in the study. Most SWCUs were based in hospitals (n=15, 35.7%) or healthcare centres, covering a specific healthcare area (n=17, 40.5%). SWCU coordinators were primarily nurses (n=33, 78.6%). Staff members' professions in SWCUs included registered nurses (n=38 units, 92.7%), nursing assistants (n=8 units, 19.5%), podiatrists (n=8 units, 19.5%), vascular surgeons (n=7 units, 17%), osteopaths (n=2 units, 4.8%) and medical doctors from different specialties (n=3 units, 7.2%). For

wound aetiology, the most prevalent wounds managed were diabetic foot ulcers (n=38 units, 90.5%), followed by venous leg ulcers (n=36 units, 85.7%) and arterial ischaemic ulcers (n=36 units, 85.7%). A statistically significant association was found between the number of staff members in a SWCU and the existence of resistance/opposition barriers when developing a SWCU (Chi-square test, $p=0.049$; Cramér's $V=0.34$; 34%), as well as between resistance/opposition barriers when developing a SWCU and a nurse as coordinator of a SWCU (MacNemar test, $p=0.007$, Cramér's $V=0.35$; 35%).

Conclusion: The typical SWCU implemented in Spain is located in a hospital or integrated in a healthcare structure that offers coverage to a whole health area and providing services for people with hard-to-heal wounds (wound management and prevention) and health professionals (advice, consultancy and training/education). Despite the growing number of SWCUs in Spain, the future of this new organisational model is uncertain, as there can be barriers to creating them and some deficiencies, such as low staff numbers, which need to be addressed.

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epidemiology • quality of care • wound care staff • wound clinics • wound management • wound healing • wounds

Hard-to-heal wounds encompass a wide range of lesions, such as pressure ulcers (PU, also known as pressure injuries), lower extremity ulcers and diabetic foot ulcers (DFUs), among others.¹ A hard-to-heal wound has been defined as one that fails to heal with standard therapy in an orderly and timely manner.² Their complexity is determined by a number of factors that may influence healing, such as patient-related factors (pathology, medication), wound-related factors (dimensions, presence of infection or ischaemia), the skills and knowledge of clinicians, and treatment-related factors (availability or cost).¹⁻² Hard-to-heal wounds are a frequent and complex challenge for clinicians, as their management usually requires the

participation of different approaches and disciplines, such as vascular or general surgery, dermatology, nursing or podiatry, among others.^{1,3}

Hard-to-heal wounds are a serious public health concern, since they are associated with high morbidity and mortality, and affect an increasing number of people worldwide.³⁻⁵ Because of their aetiological heterogeneity and the fact that most epidemiological studies have focused on one specific type of wound,⁶ the prevalence estimates for hard-to-heal wounds vary widely between different regions, countries and study methodologies.⁶ By analysing a number of different studies with heterogeneous methodology and populations studied, Queen estimated a minimum of 20 million people with hard-to-heal wounds and 400 million people with wounds in general, worldwide.³

Hard-to-heal wounds also entail huge economic costs to healthcare systems, both direct and indirect, which are higher when complete healing cannot be achieved.^{4,5,7,8} Additionally, they are associated to a significant loss of wellbeing and quality of life for patients with the consequent social impact.^{9,10}

Hard-to-heal wounds are expected to increase worldwide, due to the increase in incidence of diabetes, obesity and ageing of the worldwide population.^{5,6}

The organisational model of specialised wound care units/clinics (SWCUs) can be framed within the various

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possible theoretical or practical approaches to the growing concern about hard-to-heal wounds.¹¹⁻¹³ These wound care management approaches include the specific training and specialisation of healthcare staff, the development of certification and accreditation systems or the implementation of clinical practice standardisation instruments, such as clinical practice guidelines. Such SWCUs are heterogeneous and are called by different names depending on the geographical area or country where they are located.¹²⁻¹⁴ In general, they share a common characteristic—they are established around an organisational system based on a unified department service, integrating professionals from different disciplines.¹²⁻¹⁵ This organisational model highlights the importance of adopting an interdisciplinary/transdisciplinary approach with a teamwork perspective, for effective management of such wounds.^{13,15-17} Moreover, telemedicine elements are often involved.^{11,18,19}

The SWCU model is well established in some countries (for example, the UK, Denmark, the US and the Netherlands)^{13,20-23} and the number of such SWCUs, both for a particular type of wound or for all wounds in general, has increased in recent years.¹³ However, despite the growing interest in specialised wound care centres, published studies on this topic are limited.¹³ In Spain, information on the number, distribution, management and characteristics of these centres is scarce.

The main objective of this research was to determine the number of SWCUs in Spain and to describe their main characteristics. Studying these units may contribute to further developing this healthcare model for people with hard-to-heal wounds, as well as to deal with possible barriers that might hinder or prevent its implementation and dissemination. Having up-to-date information available on this subject may promote the development of new SWCUs in Spain and give visibility to those units already established.

Methods

Study design

This study was framed within the context of a PhD thesis by the first author. It was conducted using an observational, cross-sectional, analytical, multicentre design, on a population of SWCUs located in Spain. Inclusion criteria were:

- Organisational structures aimed at providing comprehensive care for people with hard-to-heal wounds through the use of a pre-established methodological model, focused on clinical efficiency, sustainability and improved functioning of the healthcare system they belong to, and which served as a framework for hard-to-heal wound care within the healthcare system. Such structures had to operate at an organisational level, based on a unified department/service
- Organisational structures which, in addition to the above criteria, offer information, training/education, consultancy or advice to health professionals, through

direct references or remote telematic consultations, in the field of hard-to-heal wound care.

No distinction was made regarding the level of care (hospitals, specialised outpatient clinics or primary healthcare centres) or the legal/administrative context (public, private or university centres), where the units operated. Organisational structures focusing on a particular type of hard-to-heal wound (for example, diabetic foot units) were also included. Exclusion criteria were:

- Organisational structures not clearly recognised as such, i.e., structures operating informally without a clear legal framework, were excluded from the study
- Organisational structures which, although routinely caring for patients with hard-to-heal wounds, have not been designed and are not operated exclusively or specifically for such patients (for example, burn units, vascular surgery services, general surgery services, plastic surgery services).

Questionnaire development

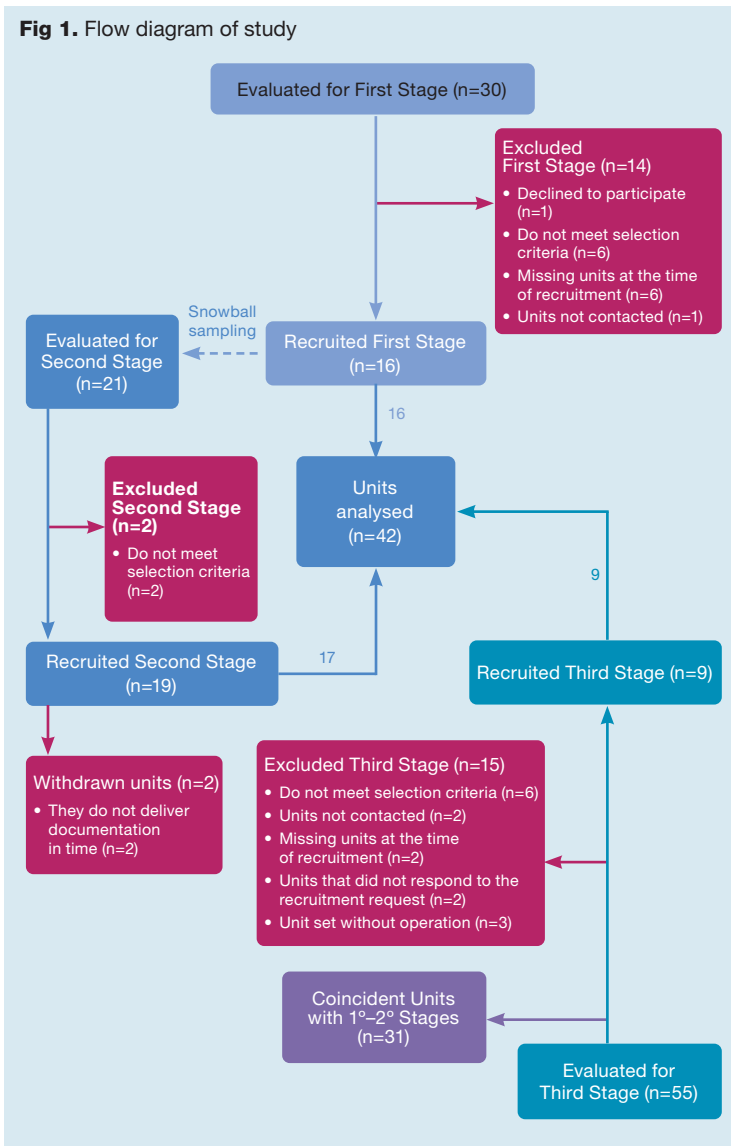
Firstly, a data collection questionnaire^{24,25} was specially designed, using a modified Delphi approach, with the collaboration of 10 wound care experts.

There are different approaches to developing a questionnaire 'de novo'. After a literature review and development of a pre-questionnaire, designed to get consensus and agreement between the expert group, different methods could be applied, such as focus or discussion groups or a Delphi method. In this study, a modified Delphi method was selected due to the characteristics and location of the experts involved. A Delphi approach enables information gathering without the physical presence of participants and helps avoid issues such as the potential for one participant to influence another, i.e. participants are blinded to each other.

The group of experts came from different Spanish regions and consisted of eight registered nurses, a medical doctor and a podiatrist. As an essential requirement, none of the participating experts was working in or with a SWCU. This was considered fundamental in order to avoid biases favouring possible aspects associated with any particular SWCU when developing the questionnaire. The modified Delphi method included three rounds plus a final round. A final questionnaire was produced with 49 items distributed across four dimensions/areas with a content validity index (CVI-Total) for pertinence=0.96 and a CVI-Total for relevance=0.94. The content validity indexes for each individual item (CVI-i) (with a likely random agreement correction (Pa) and statistical calculation of the modified Kappa (K*)) were calculated, as well as the content validity indexes for each expert (CVI-e).^{24,25}

Once the questionnaire was finished, recruitment was started. Recruitment of potential SWCUs was chronologically divided into three stages with three different and complementary sampling methods, explained below (Fig 1):

Fig 1. Flow diagram of study



- **Stage 1:** a convenience non-probability sampling, conducted by the main researcher and three experts in the field. The three experts were members of the National Advisory Group of Pressure Ulcers and Other Chronic Wounds in Spain (GNEAUPP), were recognised experts in the field of hard-to-heal wounds in Spain and were also the authors of the only document published about SWCUs in Spain at that time.¹¹ Each expert and the main researcher independently listed all possible SWCUs, to the best of their knowledge. After comparing and pooling the four lists, an initial list of units, which could possibly be included in the study, was produced
- **Stage 2:** exponential discriminant snowball sampling through interviewing SWCU coordinators recorded in Stage 1. This sampling stage was carried out through the units' coordinators, or other persons in charge or collaborating with the main researcher or the experts, who had been contacted during the first

stage. The SWCU coordinators were asked if they knew of other SWCUs

- **Stage 3:** convenience non-probability sampling, which served as 'control feedback', using the databases of three commercial companies (Smith+Nephew, Convatec and Urgo) related to the hard-to-heal wound market. Initially, six companies were contacted but only three of them eventually agreed to participate in the study. Each company sent a list of SWCUs known to their executives or sales staff to the main researcher of the study.

After the sampling process was complete, all potential SWCUs were evaluated to delete duplicates and the remaining SWCUs were contacted for recruitment. SWCUs were contacted via telephone and/or email to the unit coordinator. The recruitment process included: presentation of the research, rigorous verification of inclusion/exclusion criteria, explanation of the practical aspects of participation and information on the ethical/legal aspects of the research, such as the data confidentiality policy, publication of the study results and the criteria for withdrawal from the study.

Criteria for withdrawal from the study were:

- Units whose staff members refused consent for data obtained from them to be disclosed
- Breach of participation rules regarding confidentiality
- Failure to provide the necessary documents or the informed consent for participation
- Late delivery of the necessary documents (i.e., after agreed deadline). Following the recruitment of a unit, the main researcher submitted the documents necessary for participation to the unit's coordinator by certified mail.

The authors posted the questionnaire to the identified units. The coordinator of every unit was responsible for completing and returning the questionnaire, together with a signed informed consent form to the main researcher. The data collection period was April 2015 to December 2016.

Statistical analysis

Data were stored, processed and analysed using the statistical program for the social sciences, SPSS, version 19.0 (IBM, US). The analysis was carried out by the main researcher (first author). A descriptive analysis of the considered variables was carried out; qualitative variables were expressed as percentages and frequencies, while quantitative variables were expressed as median, mode and standard deviation (SD). Additionally, an analytical-inferential analysis of possible association or dependence between pairs of variables was conducted using the Chi-square test for qualitative variables and the Fisher's exact test. Association was considered to be statistically significant for p-values lower than the significance level established for this study ($\alpha=0.05$). Additionally, the Cramér's V coefficient was calculated, and the McNemar's test was conducted.

After completion of the PhD dissertation (of which this paper forms a part), a census of SWCUs included in

the study was published (not the results presented in this article). The previously published census includes the names, locations and care levels of the SWCUs that have participated in this study. The census was published in Spanish.²⁶

Ethical approval and data confidentiality

Because this research did not involve any intervention or data collection on patients, and also data were obtained as aggregates, no authorisation was required from an ethics committee, although certain ethical/legal issues were considered. This was because some of the information requested could be considered sensitive to the reputation of the institutions involved. All unit coordinators, who agreed to participate, were asked to sign an informed consent form. An information management policy was established, of which all participants were duly informed. According to this policy, data from every unit were to be presented for publication of results in a disaggregated way, so that it was not possible to associate the results with any specific SWCU.

Only five variables would be presented as non-disaggregated data (name of the unit, region where located, year of unit creation, healthcare organisation responsible for the unit and healthcare level at which the unit was operating).

In order to preserve data confidentiality, every SWCU was assigned an identification code, known only to the researchers. Data collected during the research were treated and stored according to the current data protection regulations, being only accessible to the researchers, who are responsible for custody of the data for a period of 10 years. The companies that participated in the third sampling stage were also assigned a code to protect their confidentiality.

Results

A total of 75 units, which were possible study candidates, were identified through the three sampling stages. From these, 31 were excluded. Of the remaining 44 included units, a further two units were eventually withdrawn (Fig 1). Thus, a total of 42 units from 13 regions of Spain were analysed.

Recruited units included those located in hospitals (n=15, 35.7%) and in healthcare centres that covered a healthcare area (i.e., integrated health organisations, n=17 units, 40.5%). The remaining units were based in primary healthcare centres (n=3, 7.1%), private medical offices (n=3, 7.1%), specialised outpatient clinics (n=2, 4.8%) or universities (n=2, 4.8%).

According to the target population, most units provided assistance at a regional level (n=18, 42.9%), followed by units providing assistance at a local level (n=11, 26.2%), at the community level (i.e. one of the Spanish autonomous communities, n=10, 23.8%), at the national level (n=2, 4.8%) and the international level (n=1, 2.4%).

In terms of working hours, four schedules were considered:

- Units providing assistance during some hours of the day on working days (hour restriction)
- Units providing assistance during some hours of the day only on some working days (day-hour restriction)
- Units providing assistance 24 hours every day, although with staff restrictions during the night, weekends and holidays (24 hours with restrictions)
- Units which were always on duty without staff restrictions (24 hours without restrictions).

Most units provided assistance with 'hour restriction' (n=28, 66.7%), followed by 'day-hour restriction' (n=6, 14.3%), '24 hours with restrictions' (n=4, 9.5%), and '24 hours without restrictions' (n=4, 9.5%).

Regarding SWCU facilities, 39 units (92.9%) offered assistance in 'boxes' (a room specifically for treating people with wounds), 27 (64.3%) units had a 'warehouse for medical equipment', 24 (57.1%) units had 'telemedicine rooms', 23 (54.8%) units had 'patient reception rooms', 10 (23.8%) units had 'operating rooms for minor surgery', and seven (16.7%) units had 'rooms for prosthesis offloading'.

SWCU coordinators

Regarding the qualification of SWCU coordinators, most were nurses (n=33, 78.6%), followed by medical doctors (n=6, 14.3%) and podiatrists (n=3, 7.1%). All of the medical doctors were specialist doctors: five (11.9%) were angiologist-vascular surgeons and one (2.4%) was a general surgeon.

The education degree of coordinators' included: MSc (n=19, 45.2%), PhD (n=9, 21.4%), diploma degree (three years' duration in Spain, n=10 (23.8%)) and bachelor's degree (4–6 years' duration in Spain, n=4 (9.5%)). Furthermore, 21 (50%) coordinators had received postgraduate training specifically in hard-to-heal wound care, 16 (38.1%) had received official accreditation from GNEAUPP, and seven (21.2%) of those without a PhD, were in a PhD programme at the time of recruitment and questionnaire administration. The professional experience of unit coordinators ranged from 11–41 years (mean=27.4±8.0 years; median=26.0; 95% confidence interval (CI)=24.8–29.9).

SWCU staff members

On average, 2.8±2.7 staff members (median=2.0; range: 1–15; 95% CI=1.9–3.6) were working in a SWCU. Many SWCUs had only one staff member (n=19; 45.2%). Regarding the professions of SWCU staff members, the majority were nurses (n=38; 90.5%), followed by nursing assistants (n=8, 19.0%), podiatrists (n=8, 19.0%), angiologist-vascular surgeons (n=7; 16.7%), osteopaths (n=2; 4.8%) and doctors from different specialties (n=3; 7.1%). Only six units (14.3%) had staff members from different professions (three or more), while 25 (59.5%) units did not have a multidisciplinary team.

Besides the staff at SWCUs, two additional types of auxiliary teams were considered, based on a GNEAUPP position document;¹¹ 'consultant team' and 'support team'. Table 1 shows the disciplines and clinicians

Table 1. Disciplines/professionals integrated in ‘consulting and support teams’ in specialised wound care units/clinics (SWCU) (n=42)

Professional/discipline/department	Consulting team, n (%)	Support team n (%)	Total n (%)
Department of angiology vascular surgery/vascular surgeon	19 (45.2)	12 (28.6)	31 (73.8)
Endocrinology nutrition service	11 (26.2)	8 (19.0)	19 (45.2)
Department of plastic surgery/plastic surgeon	14 (33.3)	5 (11.9)	19 (45.2)
Dermatology service/dermatologist	9 (21.4)	8 (19.0)	17 (40.5)
Traumatology service/traumatologist	7 (16.7)	7 (16.7)	14 (33.3)
Department of internal medicine	6 (14.3)	7 (16.7)	13 (31.0)
Department of general surgery/general surgeon	8 (19.0)	5 (11.9)	13 (31.0)
Microbiology service/microbiologist	7 (16.7)	2 (4.8)	9 (21.4)
Wound nurse practitioner	6 (14.3)	3 (7.1)	9 (21.4)
Rehabilitation service/prosthetic team	6 (14.3)	3 (7.1)	9 (21.4)
Social work assistant	0 (0.0)	8 (19.0)	8 (19.0)
Radiodiagnostic/radiology service	1 (2.4)	7 (16.7)	8 (19.0)
Case management nurse	2 (4.8)	3 (7.1)	5 (11.9)
Podiatrist	3 (7.1)	2 (4.8)	5 (11.9)
Geriatrics service	4 (9.5)	1 (2.4)	5 (11.9)
Department of anaesthesia/pain unit	4 (9.5)	1 (2.4)	5 (11.9)
Diabetes nurse educator	1 (2.4)	3 (7.1)	4 (9.5)
Others	11 (26.2)	20 (47.6)	31 (73.8)

Consultant team: a consultant team was considered to be composed of one or more staff members who, although not working full-time at the clinic, regularly collaborated with the staff by providing advice and participating in clinical processes; Support team: a support team was considered to be composed of staff members who were not working at the SWCU regularly, but occasionally (less than 5 consultations, collaborations or actions per year). Translated and based on García-Fernández et al.¹¹

integrated in the ‘consultant’ and ‘support’ teams identified. Both ‘consultant’ and ‘support’ teams were available for 22 (52.4%) units. For 11 (26.2%) units a ‘support team’ only was available, and for eight (19.0%) units, a ‘consultant team’ only was available, while none of the considered teams was available for one unit (2.4%).

Services provided by SWCUs

Most SWCUs (n=40, 95.2%) provided services for people with hard-to-heal wounds (wound management and prevention) and health professionals (advice, consultancy and training/education). All but one unit provided advice to health professionals from other centres; email was the most frequently used communication system (n=37; 88.1%); other systems included: telephone call (n=36; 85.7%), healthcare-management software (n=32; 76.2%), specific computer programmes for wounds (n=19; 45.2%), instant messaging, for example, WhatsApp (n=19; 45.2%) and social networks (n=9; 21.4%). Communication systems were not considered mutually exclusive.

Consultation topics were classified into three broad groups:

- Advice on wound diagnosis
- Advice on wound treatment
- Advice on wound prevention.

These categories were scored according to frequency, ranging from one (most frequent) to three (least frequent). Only 35 (83.3%) units completed this item on the questionnaire. Most frequent consultations were ‘Advice on wound treatment’ (scored 1 in 28/35 units completing this item; 80.0%), followed by ‘Advice on wound diagnosis’ (scored 1 in 5/35 units; 14.3%), and finally ‘Advice on wound prevention’(scored 1 in 2/35 units; 5.7%).

Besides providing direct patient care at the SWCU, 33 (78.6%) units also provided care at other clinical departments different from the SWCU, and 18 (42.9%) units provided home care.

Classifying SCWUs by aetiology, the most frequent wounds dealt with were: DFUs (n=38, 90.5%), followed by venous leg ulcers (VLUs, n=36, 85.7%), arterial ulcers (n=36, 85.7%), complicated surgical wounds (n=35, 83.3%), PUs (n=34, 81.0%), open surgical wounds (n=32, 76.2 %), moisture lesions (n=31 units, 73.8%), low prevalence atypical wounds (n=30 units, 71.4%), burns (n=21, 50.0%) and other wounds (n=27, 64.3%).

Table 2. Therapies, types of debridement and methods of diagnosis used in specialised wound care units/clinics (SWCU)

Therapies	SWCU (n=41*), n (%)	Method of diagnosis	Wound units (n=42), n, (%)
Moist wound healing dressings	41 (100.0)	Ankle-brachial pressure index	39 (92.9)
Offloading	34 (83.0)	Blood test	35 (83.3)
Compression therapy	33 (80.5)	Monofilament	34 (80.9)
Negative pressure therapy	33 (80.5)	Conventional radiology	33 (78.6)
Traditional dry care (dry gauze)	30 (73.2)	Tuning fork	32 (76.2)
Tissue engineering	16 (39.1)	Doppler ultrasound	29 (69.0)
Physical therapy	12 (29.3)	Arteriography	26 (61.9)
Hyperbaric therapy	8 (19.6)	Toe pressure index	25 (59.5)
Alternative/natural therapy	7 (17.1)	Nuclear magnetic resonance	25 (59.5)
Genetic therapy	4 (9.8)	Gammagraphy	23 (54.8)
Maggot therapy	4 (9.8)	Computerised axial tomography	23 (54.8)
Type of debridement		Transcutaneous oximetry	22 (52.4)
Enzymatic	41 (100.0)	Metalloproteases tests	21 (50.0)
Sharp	40 (97.6)	Advanced hot-cold exploration	21 (47.6)
Autolytic	40 (97.6)	Pedobarography	19 (45.2)
Osmotic	28 (68.3)	Neuropad	17 (40.5)
Surgical (in a theatre)	18 (43.9)	Neurotip	16 (38.1)
Mechanical	14 (34.2)	Neurothesiometer	15 (35.8)
Jet/hydro surgery	12 (29.3)	Touch-test discriminator	14 (33.3)
Ultrasound	5 (12.2)		

*One SWCU did not offer direct care to patients and so this unit was not included in the calculations

The different therapies, debridement types and methods of diagnosis used at SWCUs are shown in Table 2.

Of the participating SWCUs, 40 (95.2%) took part in educational activities at their centres; although only 30 (71.4%) participated in educational activities for patients and 24 (57.1%) units in educational activities for university training. Regarding research activities, 30 (71.4%) units participated in 'studies sponsored by

private companies', 28 (66.7%) units in 'non-sponsored studies', 13 (31.0%) units in 'international research projects' and only seven (16.7%) participated in 'studies funded by public agencies'.

Systems to evaluate clinical efficacy and other operational aspects of SWCUs

In the study, five possible systems, which were not mutually exclusive, were considered to evaluate the clinical efficacy of SWCUs (Table 3). From 42 analysed units, only two (4.8%) did not use any of the systems. Given that the most widespread system consisted of the use of 'quality indicators' (n=34 out of 40 who used it, 85.0%), a further analysis was conducted in terms of two parameters: the used indicators (Table 4) and the number of used indicators. SWCUs used 5.2 ± 3.0 quality indicators (median=4.5, 95% CI=4.1–6.3; range: 1–13).

A further analysed parameter was 'exchange of professionals', i.e. external professionals coming to collaborate in the SWCU or staff members working in other units with the aim of improving their training. Results showed that 'external' professionals had come to collaborate in 32 (76.2%) units, while staff members of only 13 (31.0%) units had rotated to different units.

Table 3. Systems to evaluate clinical efficacy at specialised wound care units/clinics (SWCU)

Systems	SWCUs* (n=40), n (%)
Quality indicators	34 (85.0)
Annual activities report	32 (80.0)
Patient satisfaction surveys	12 (30.0)
Prizes/awards for welfare work	8 (20.0)
External audits	5 (12.5)

*Only 40 SWCUs used systems to evaluate clinical efficacy

Table 4. Quality indicators used at specialised wound care units/clinics

Quality indicators	Units (n=34), n (%)
Prevalence	31 (91.2)
Incidence	24 (70.6)
Proportion of wounds healed	20 (58.8)
Rates of infection	16 (47.1)
Rates of recurrence	13 (38.2)
Cost-effectiveness	10 (29.4)
Major amputation rate	10 (29.4)
Minor amputation rate	10 (29.4)
Mortality rates	9 (26.5)
Total cost management	9 (26.5)
Days of hospitalisation linked to wound	8 (23.5)
Percentage wound area reduction	7 (20.6)
Change in wound rating score	7 (20.6)
Quality of life score	6 (17.6)
Number needed-to-treat	1 (2.9)
Cost per quality-adjusted life year (QALY)	0 (0.0)

Barriers to implementing a SWCU

Possible barriers affecting the development of SWCUs or their current operation were analysed, and five types of barriers were defined:

- Financial/economic
- Legal/regulatory
- Resistance/opposition
- Logistical
- Other

The possible influence of these barriers, both on the development and current operation of the selected SWCU, was analysed. Of the participating units, 31 (73.8%) units reported barriers affecting their creation, while nine (21.4%) units indicated that they had not encountered barriers. Regarding barriers affecting the SWCUs' current operation, 31 (73.8%) units reported operational barriers, and 11 (26.2%) units reported no barriers (Fig 2).

Inferential analysis

Possible associations were explored between the existence of barriers and different variables by using different statistical tests. In particular, the association between 'Resistance/opposition barriers' (both affecting development or its current operation) and the following variables: 'number of staff members in the SWCU', 'existence of a multidisciplinary team', 'nurse as SWCU coordinator' and 'existence of a consultant team' was analysed.

The Chi-square test showed a significant association

between 'Resistance/opposition barriers to the development of the SWCU' and the 'existence of a multidisciplinary team' (p=0.049). Given the small sample size, Fisher's exact test was also used, although no significant association was found with this test. The Cramér's V coefficient showed associations between 'Resistance/opposition barriers to the development of SWCUs' and the 'number of staff members in the SWCU' (Cramér's V=0.34/34%), as well as between 'Resistance/opposition barriers to the development of SWCUs' and the 'existence of a multidisciplinary team' (Cramér's V=0.35/35%). No statistically significant association was found between 'Resistance/opposition barriers to the current functioning of the SWCU' and any of the considered variables. The McNemar's test showed statistically significant association only between 'Resistance/opposition barriers to the creation of the SWCU' and 'nurse as the SWCU coordinator' (p=0.007).

Discussion

A main objective of this study was to identify SWCUs located in Spain. This would, in effect, be the first SWCU census in Spain.²⁶

According to the study data, SWCUs are dynamic organisations, subject to frequent changes, including the possibility of disappearing. From the initial potential candidate units, eight units had already closed by the time of recruitment. The study design precluded exploration of the causes; however, it can be speculated that as this organisational model is rather novel, where SWCUs fail to prove useful, this may account for their disappearance. In addition, SWCUs often begin operating informally and only acquire a formal unit status after some time.¹⁷ During the course of this research, a number of potential SWCUs operating informally, without a clearly established or regulated legal framework, were found. This situation evidences that hard-to-heal wounds are a growing concern that forces health organisations to seek organisational responses.²⁷ Potential SWCUs were also found; these included professionals from a certain specific service (mainly vascular surgery, general surgery or similar) but which had not taken the definitive step to formally establish themselves as a distinct entity, apart from this service.^{12,15} Some of these structures could be considered possible future SWCUs and are a sign that the hard-to-heal wound challenge requires new organisational models.^{15,17}

In terms of location of SWCUs, most were in hospitals, or integrated in healthcare structures that covered an entire healthcare area (structures consisting of a group of hospitals, healthcare centres and socio-sanitary centres, i.e. an integrated healthcare organisation). Other SWCU locations were less frequent, especially when compared with other countries, where university or private medical offices are important.¹⁵ In general, we consider hospitals to be the most favourable environment for SWCU location, since human and material resources for effective wound care are most

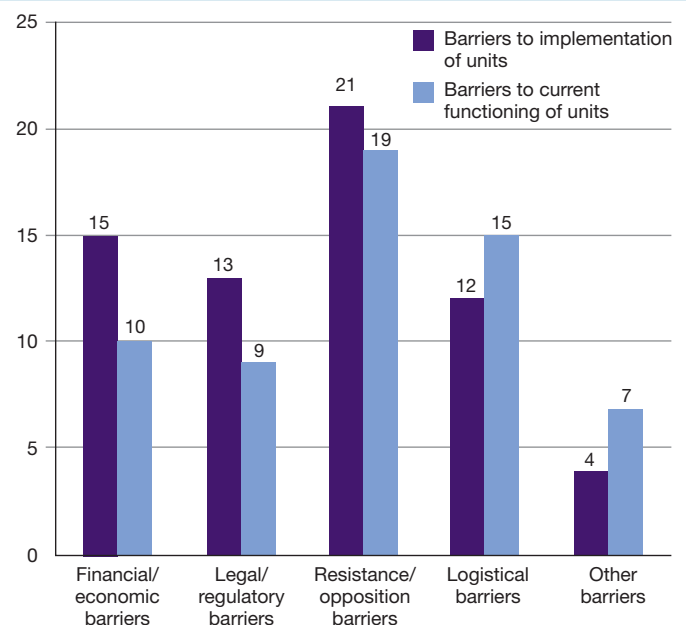
accessible in this setting.^{11,14,21,22}

The Spanish National Health System is fragmented into 17 subsystems, one for each regional community in Spain and each with its own particularities of organisation and structure. This makes it difficult to find common points or links that help understanding of the SWCU issue at a national level. Nevertheless, the SWCUs studied seem to fall within the unit types previously established by Professor Gottrup (one of the pioneers of the wound healing centre model), where the ideal clinical model for a wound healing centre would most likely be an independent clinical multidisciplinary department treating all types of complex wounds. Such a centre would consist of an outpatient clinic and an inpatient ward with beds only for patients with wounds. This model is dependent on multidisciplinary, well-educated and trained personnel working full-time with complex wounds and taking care of patients throughout their entire treatment course.²⁸ Thus, the general profile of SWCUs in Spain includes clinics aimed at caring for patients with different types of hard-to-heal wounds, together with SWCUs focused on patients with a specific type of wound, most frequently diabetic foot. Also, most SWCUs offer 'support', 'education' or 'advice' to other clinicians, mainly through telematic systems. Nowadays, telematic systems are considered to be an efficient tool for the management of several aspects of hard-to-heal wounds. Furthermore, they enable information exchange and facilitate clinical decision-making.^{11,29} Successful experiences with the use of these systems in the management of hard-to-heal wounds have been reported.^{19,30}

Diabetic foot is the most frequently managed type of wound at the SWCU, some of which specialise in its treatment and management. The scale of the challenge associated with diabetic foot is clear,^{7,17,31,32} as is the need to adopt a SWCU model to address it.^{17,31,33,34} In addition, VLU and arterial ulcers are also frequently managed. It is a matter of concern that PUs are among the most common types of treated hard-to-heal wounds, because these lesions are potentially preventable;³⁵ however, they remain a significant challenge in Spain.³⁶ Although the conceptual framework of moisture lesions is relatively new, they have also been confirmed as lesions with a high demand for care.^{37,38} A further remarkable outcome is the large number of wounds derived from surgical procedures managed at the SWCU, which reinforces the proposal that SWCUs should be seen as valuable support structures for surgical service departments.^{12,21}

Regarding treatment options, moist wound healing dressings were the 'stars' of therapeutic treatments, as they were used in all the SWCUs. Moist wound healing dressings are framed in the context of wound bed preparation and its effectiveness has been demonstrated.^{2,39,40} Choosing suitable dressings and products is a challenge as the variety of dressing types has grown enormously in recent years, thus contributing to the complexity of the process.^{41,42} We postulate that

Fig 2. Comparison between the barriers in the implementation of the units and in their current functioning. **Financial/economic barriers:** economic obstacles or problems. **Legal/regulatory barriers:** obstacles or problems derived from regulatory and administrative aspects, which might have hindered the creation of the unit or its current functioning. **Resistance/opposition barriers:** obstacles to the establishment or functioning of the specialised wound care unit, derived from resistance/opposition to a new organisational structure in the centre, lack of interest or lack of support from the centre's manager or other professionals. **Logistical barriers:** obstacles or problems of a practical nature. **Other barriers:** obstacles or problems that cannot be framed in the previous categories, according to the criterion of the unit coordinator



the role of 'health professional specialised in wound care' will rise in the coming years. Some of the SWCUs in this study are already considering including such professionals. In our opinion, SWCUs should lead policies aimed at optimising the correct and efficient use of such dressings.

Negative topical pressure therapy and compression therapy are also extensively used. There is a good body of evidence to support their effectiveness in the treatment of particular hard-to-heal wounds, such as leg ulcers and diabetic foot ulcers.⁴³⁻⁴⁵ Other therapies are less often used, for example larval therapy and hyperbaric oxygen therapy. Larval therapy has a long history and is a well-documented technique, commonly used in many European countries.⁴⁶ Hyperbaric oxygen therapy is a well implanted technique in countries where the SWCU model is established, for example in the US, where many certifications for specialisation in hard-to-heal wounds are linked to training in hyperbaric medicine.^{47,48} The use of both of these therapies in Spain is rather limited. Debridement is a basic strategy in the management of any type of hard-to-heal wound.^{2,39,40,46} We observed that in our recruited SWCUs, traditional debridement methods (sharp, autolytic and enzymatic) prevail over more advanced or

novel systems (for example, hydrosurgery or ultrasound).^{46,49}

Diagnostic tools or systems available at the included SWCUs were analysed. It has been claimed that 30% of hard-to-heal wounds lack a clear and accurate diagnosis.⁴ According to our findings, only 50% of SWCUs had access to tests for measurement of metalloprotease levels, a specific technique used in hard-to-heal wounds, that has risen in prominence in recent years.⁵⁰ This technique is necessary to support the use of protease modulating dressings.⁵⁰ Diagnostic tests to establish the degree of lower limb ischaemia are essential for diagnosis and subsequent choice of an effective treatment in lower limb wounds (VLUs, ischaemic ulcers, DFUs).^{2,39,40} With that purpose, the ankle-brachial pressure index (ABPI) is calculated; this has traditionally been based on the use of Doppler, although transcutaneous oximetry (TcPO₂) has become increasingly important in the last few years.^{39,51} TcPO₂ was available in about 50% of the participating SWCUs. However, ABPI is the diagnostic test with the highest degree of implementation. Although the ABPI has certain limitations and has been recently questioned (especially regarding its use in patients with diabetes or its application by non-expert personnel),⁵²⁻⁵⁴ it is accepted that the ABPI should be a routine measurement.^{39,55} Only two specific diabetic foot tests (monofilament and tuning fork) were available in >50% of the SWCUs. Other specific diabetic foot tests were generally unavailable. This is important because some studies highlight the disparity of results, when comparing different diagnostic tests for neuropathy, as well as the need to combine different tests to obtain adequate risk stratification in diabetic foot.^{56,57}

A desirable characteristic for a SWCU is to serve as a platform to increase the visibility of the challenge of hard-to-heal wounds and to promote research in this field, given the known lack of solid evidence regarding these wounds.^{58,59} Data indicate that SWCUs in Spain develop considerable research activity, although their participation in international projects should be improved. In the same way, there is a well-established need for educational activities and training in SWCUs. Of note is that 57.1% of SWCUs in Spain did not have any relationship with a university. For example, university nursing programmes in Spain include limited and insufficient hard-to-heal wound care content.⁶⁰ In this regard, Denmark and the model led by Gottrup pioneer the way.^{61,62}

Recent trends in Europe aimed at shifting from hospital care to home care.⁶³ This approach, however, is not widespread in Spain, since only 42.9% of SWCUs provide home care to patients.

We were interested in investigating ways to assess the clinical efficacy-efficiency of SWCUs. We established five systems that are not mutually exclusive. The most widespread method is based on the use of quality of care indicators. However, there are still no reliable quality indicators in the field of wound care,^{13,64} although

many have been proposed and are attracting increasing interest.^{13,64,65} Therefore, we chose 16 possible quality indicators for hard-to-heal wound care. Prevalence and incidence rates are the most extensively used indicators and are accepted as basic measures, in particular for PUs. In this regard, incidence is considered a better indicator of the quality of care.^{66,67} The rate of amputation (both minor and major) is not often used, despite being considered a good indicator of the quality of care in patients with diabetic foot.^{65,68,69} Cost-based indicators are scarcely used. However, indicators of efficient management of available resources are important⁶⁹ and may support the adoption of the SWCU model, from the perspective of health organisation managers.^{20,21,70} Indicators based on quality of life are also scarcely used, despite the growing interest in this subject.^{9,10,69}

We found that SWCUs were usually open to receiving staff from outside the unit. However, SWCU staff members were generally reluctant to make external rotation themselves.

Information on SWCU coordinators is important for understanding the development and establishment of SWCUs and thus, the possible implementation of that model.^{17,31} In Spain, most coordinators are nurses. Given the well-documented historical relationship between wound care and nursing,^{4,71} this is not a surprising result.²² Most medical doctor coordinators were angiologists and vascular surgeons. In hard-to-heal wound care, knowledge and experience are equally important.⁷² Our data indicate that SWCU coordinators are experienced professionals with an extensive professional career, well adapted to their leading role. However, availability of suitably trained and experienced professionals, who might take over in the future, is seen as necessary to prevent units from disappearing.

Requirement for accreditation/certification, which is highly developed in some countries,^{47,73,74} is not so extensive in Spain. This may account for the fact that few SWCU coordinators have relevant certifications. Some organisations, such as the European Wound Management Association (EWMA), have proposed the development of accreditation/certification systems for SWCUs,⁷⁵ which would ensure that staff fulfil the necessary requirements.

In general, Spanish SWCUs are clinical structures with reduced staff, as compared with a typical hospital department. However, it should be kept in mind that SWCUs often emerge from established departments^{15,23} and that they are a relatively recent phenomenon,¹⁴ all of which entails operational constraints. In our opinion, it is a matter of concern that 45.2% of the SWCUs in Spain have only one staff member. According to Attinger et al., 'a successful wound center requires considerable staff',²¹ which leads us to conclude that multidisciplinary is insufficient in Spanish SWCUs. However, as compensation, most include consulting or support teams.^{21,23,76,77} The presence of endocrinology nutrition specialists is mainly related to diabetic foot,

although it is important to highlight that nutrition often plays an undervalued role in other types of wounds.⁷⁸ All of this supports the idea that wound care management requires the participation of diverse clinicians and/or disciplines, due to the complex needs of patients with hard-to-heal wounds.^{16,75,79} Nevertheless, what is really important, more than the number of clinicians involved, is the way in which relationships between them are established. Nowadays, a transdisciplinary or interdisciplinary approach, to hard-to-heal wound care is preferred.^{16,79} An organisational SWCU model based on the establishment of a unified department service structure facilitates the adoption of any of these approaches, since it fosters professionals' feelings of belonging to a service, rather than to a specialty or discipline.

Regarding possible barriers for the development of SWCUs, although financial/economic factors influence heavily, they are not the main obstacle. Main barriers found were what we called 'resistance/opposition barriers'. Regardless of statistical significance, from a descriptive point of view, our results suggest that the presence of multidisciplinary teams or of a large number of staff members reduces 'resistance/opposition barriers'; while a nurse lead as a SWCU coordinator seems to increase resistance/opposition. Although such postulations should be further researched, our descriptive results suggest that, when organisations consider the implementation of a new SWCU, a participative approach integrating several disciplines and professionals reduces the chances of opposition.

Limitations

Some issues were identified as possible limitations or biases, potentially influencing the results of the study. Since there were no previous records of the number of SWCUs in Spain, non-probabilistic sampling was conducted. In order to minimise possible bias from the sampling system, a combined system was used, which was intended to make the process more robust. We postulate that this sampling allowed us to identify most of the Spanish SWCUs; however, we are aware that some clinics might have been missed to sampling. The fact that data collection was based on questionnaires submitted to the SWCU coordinators, i.e., information was not obtained through direct observation, may also be considered a limitation of this study.

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Another possible limitation is the scarce information published on this topic in Spain. Only one similar study carried out in our country has been published so far; however, it refers to a specific type, diabetic foot units; thus, comparison with our results should be made with caution.⁸⁰ There are also few studies that allow comparisons between our results and those in other countries.¹³ For example, the wound-care model in China is dual, including so-called wound healing centres (WHCs) and wound care units (WCUs), which differ in the profession of their coordinators and staff,²³ i.e., medical doctors lead WHCs while nurses coordinate/lead WCUs.²³

No stratification system was available to classify SWCU levels, which precludes objective comparisons. The only exception has been proposed by the International Working Group on the Diabetic Foot for classification of diabetic foot units.^{31,80} This issue remains to be addressed by researchers and societies interested in the study of SWCUs.

Although only three of six wound care companies agreed to collaborate and sent lists of potential SWCUs, and this could be seen as a limitation, the companies sent similar lists and it is unlikely that the non-participating companies could identify other SWCUs. Also, only nine SWCUs were recruited from the companies suggestions.

Conclusion

The SWCU is an organisational model that provides the opportunity to offer suitable quality of care to patients with hard-to-heal wounds, based on the best available evidence from the coordinated efforts of different disciplines and professionals.

This research deals with a topic that has been little studied in Spain. We postulate that it provides results that significantly increase our knowledge of wound care units in Spain, but also opens questions that call for new lines of research. **JWC**

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Reflective questions

- What access do you have to specialised wound units in your region? If so, what challenges do you face in accessing specialised care for your patients?
- How would a system of specialised wound units improve patient care?
- What are the benefits of nurse-led teams in wound care units?

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