

# Patient expectations “vis-à-vis” an innovative remote therapeutic device: Case of chronic wounds in diabetic patients

M. Muller\*, A. M. Foote\*, P-Y Benhamou\*, S. David-Tchouda\*, S. Xydis\*\*

\*Grenoble University Hospital, Grenoble, France

\*\*Institute of Communication and Computer Systems, Greece

Contact Info: {MMuller, AFoote, PYBenhamou, SDavidtchouda}@chu-grenoble.fr; sxydis@microlab.ntua.gr

**Abstract**—SWAN-iCare is an ambitious project which will provide a major leap forward in the management of chronic wounds, mainly diabetic foot ulcers (DFU) and venous leg ulcers (VLU). It aims at a next generation integrated solution for remote monitoring and personalized therapy of foot and leg ulcers, as well as providing an objective continuous evaluation of the wound condition, in contrast to the current subjective evaluation made by the clinician. In this paper, we present an inventory and analysis of user/patient expectations and concerns collected during patients’ “Focus Groups” held in Grenoble University Hospital. Combining remote monitoring and personalized care for wound management has immense potential, however, meeting patient expectations and addressing their concerns about a device during its development is crucial to improving its subsequent acceptance post-marketing and patient compliance. Analysis of results shows that patients’ main expectation was that the innovative device will provide improved medical surveillance of their wound, with fewer visits to the clinic or surgery. However, these patients are often elderly and ill at ease using new technologies. This suggests that operations intended to be done by patients (and carers) must be as simple as possible.

**Index Terms**—diabetic foot ulcer, remote monitoring, negative pressure therapy, focus groups, patient expectations

## I. INTRODUCTION

Foot ulcers in diabetic patients are a growing public health problem with often poor patient outcomes in terms of morbidity and quality of life. Specifically, the annual incidence of foot ulcers in the US population has been estimated at 1.9% in type 1 and 2 diabetic patients. Various European studies suggest the incidence to be 0.21% and 3.6% [4], respectively. This relatively high incidence impacts a growing population, since by the year 2025, it is estimated that 300 million people will have diabetes [1] and by 2030 nearly 438 million will be affected by diabetes [2], [3].

In recent years there has been an increased focus on getting patients out of the hospital and back into their own homes as soon as possible. In the case of wound care, some patients with complicated hard-to-heal ulcers end up needing hospitalisation for their condition. Negative Pressure Wound Therapy (NPWT) is increasingly applied in hospitals to treat this kind of chronic wound and performs by removing exudate and potentially infectious material. Although, there are many reasons for hospitalisation; some patients who require

NPWT are hospitalised simply because they require constant monitoring and immediate access to wound care specialists.

The SWAN-iCare<sup>1</sup> (*Smart wearable and autonomous negative pressure device for wound monitoring and therapy*) project aims at developing an integrated autonomous device for the monitoring and the personalized management of chronic wounds, mainly diabetic foot ulcers (DFU) and venous leg ulcers (VLU). The core of the project is the fabrication of a conceptually new wearable negative pressure device equipped with Information and Communication Technologies (ICT) that will allow clinicians to: (i) accurately monitor many wound parameters via non-invasive integrated micro-sensors, (ii) early identify infections and (iii) provide remotely an innovative personalised therapy via non-invasive micro-actuators to supplement the negative pressure wound therapy.

An important preliminary stage in the development of complex innovative medical devices is a clear assessment of the needs and expectations of the patients and healthcare professionals for whom the device is intended. This assessment should be performed at the outset of the project in order that the results can be taken into account throughout the design and development stages of the device. In this paper, we focus mainly on the analysis of a “Focus Group” [5] held with patients in order to collect their opinions vis-à-vis the innovative SWAN-iCare therapeutic device. We first provide a brief description of the main concepts and subsystems of SWAN-iCare, and then we continue with the presentation and analysis of the patients expectations and concerns.

## II. SWAN-ICARE: BRIEF INTRODUCTION

The SWAN-iCare project [6] is an ambitious multinational research project which aims to provide a significant advance in the treatment of chronic wounds, especially DFUs and VLUs. A Smart Negative Pressure Wearable Device (SNPD) will be developed that will integrate non-invasive sensors that allow objective, continuous, real-time monitoring of critical parameters with personalised therapy tailored to supporting the patients’ wound condition. The device will have the potential

<sup>1</sup>The project is supported by the European Commission under the 7th Framework Programme (FP7-ICT -20,011 to 8. Project No. 317894)

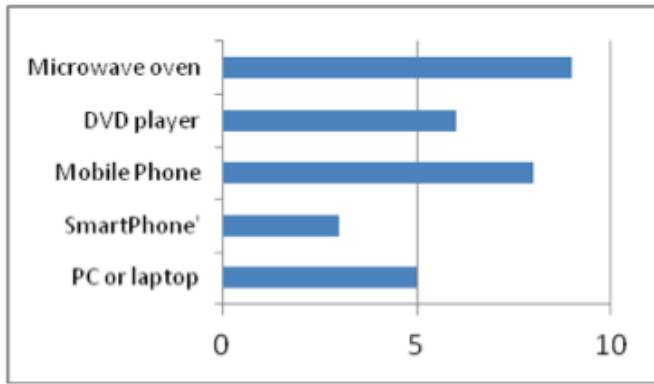


Fig. 1. Electronic equipment in the patient's home.

to remotely release active agents to assist in the wound healing process. To facilitate distant monitoring and support provided by centralised specialists to patients being cared for outside of the hospital environment, the device will be equipped with wireless technology to transmit the measured wound parameters in real-time. Thus, better remote monitoring of the wound and adaptation of the treatment at distance (e.g. by infusion of active substance into the wound) will be possible.

The SWAN-iCare infrastructure is composed of a set of subsystems namely: (i) the Clinical Back-End integrated in the hospital infrastructure which includes the back-end server where the application and database run, and one or many front-ends, where the users can interact with the system, according to their assigned roles, (ii) the Mobile Client for enabling the healthcare professionals to access the Patient data on the Server, (iii) the Home Device Area Network, i.e. one or more Stationary Medical Devices, one or more Wearable Devices and one or more External Devices, which will link to the Clinical Back-End, and the (iv) the Smart Negative Pressure Wearable Device itself that applies the negative pressure wound therapy, and provides monitoring information as well as warnings and alarms to both the patient and the clinical back-end.

### III. PATIENTS AND METHODS

In November 2012 two discussion groups, with 12 patients in total, were formed from patients who were regularly followed by the Diabetology Department of Grenoble University Hospital. Inclusion criteria included current treatment for a diabetic foot ulcer or having been treated for a DFU in the past 5 years. The discussion was led by a moderator and two observers who could help participants if needed. The discussion was preceded by a presentation of the SWAN-iCare project with slides and using prototype devices. Then a questionnaire was filled in by each patient, but with group discussion, taking care to maintain a discussion, promote exchanges on each topic and involve all the participants. Patients were encouraged to express their expectations and fears concerning the device. The entire session was audio recorded to facilitate analysis.

## IV. ANALYSIS OF RESULTS

### A. Patient characteristics

All patients were male with a mean age of 65 (56 - 82 years) and regularly attended the hospital Diabetology department. Most (83%) lived with a partner, 17% living alone. Four had left school after 8 years or less of schooling, five had between 8 and 15 years of formal education and three had continued their education beyond 15 years. Three patients stated that they did not like testing new electronic devices. Not all patients possessed even simple electronic home appliances (Figure 1). Eleven possessed a mobile phone of which three were SmartPhones. These last three patients felt they would be able to use it with the SWAN-iCare device providing that they received instruction.

### B. Medical characteristics of patients

All patients had already experienced a DFU. Seven had a DFU that was being treated at the time of the discussion group. Of these four had been under treatment for over 8 weeks and three had been treated for less than 8 weeks. Three patients had only one DFU while 9/12 had had between 2 and 4 DFU in the past five years. Only one patient had already been treated by negative pressure.

### C. Opinions about the proposed device

All patients expressed several concerns about the proposed device (Figure 2). Notably, they hoped that the device would be lightweight and discreet with little hindrance to their daily activities and their autonomy. They thought that the device should be as simple as possible to operate, particularly as the patient could not be expected to learn to do things that were too technical (Figure 3). They want to be able to control the device themselves and remain independent. The majority of patients thought that the negative pressure unit should be designed to be worn on the waist (7/12), few considered that it could be worn attached to the leg (2/12) or in the sole of a shoe (1/12). None of them wished to carry it in a shoulder-bag or satchel.

Overall, the patients were not worried about being under continuous surveillance by the wound healing center. Neither were they concerned that their treatment could be changed remotely by the clinician (change in negative pressure settings or infusion of an active substance into the wound). Their main expectation was that the innovative device would provide improved medical surveillance of their DFU, with fewer visits to the clinic or surgery. However, loss of personal contact with the medical team was stressed as a disadvantage. They expect it to provide accelerated wound healing and to be a way of avoiding amputation. They expressed the wish that carers, community nurses and their GP should be all be instructed in how to use the device. Lastly, many asked about device dysfunction: If its not working properly "what happens?", "how does one know?"

## V. DISCUSSION AND CONCLUSION

Meeting patient expectations about a device is crucial to improving its subsequent acceptance postmarketing. Using focus

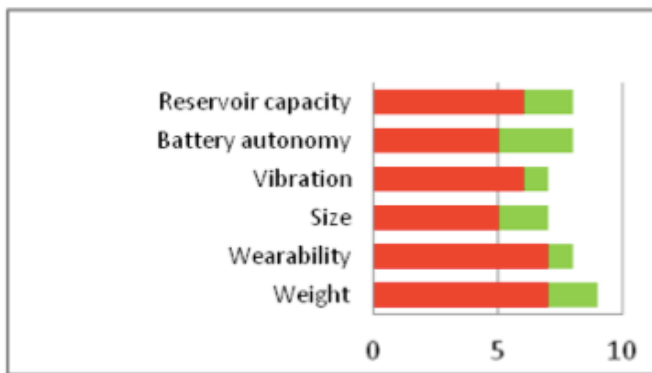


Fig. 2. Patient's Concerns about the device Red: serious concern; green: not a problem.

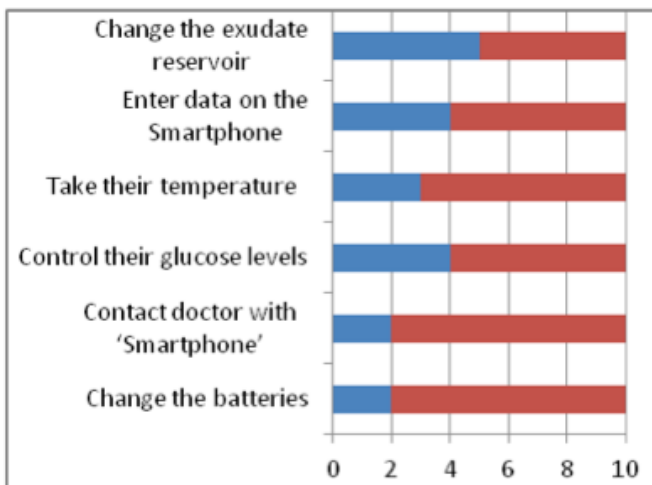


Fig. 3. Operating the device at home Blue: capable; red: incapable.

groups we were able to determine some of the expectations of patients vis-à-vis the innovative medical device for hard to heal chronic foot ulcers:

- Patients were not worried that they would be under continual monitoring and surveillance by the medical staff at the wound healing center. They were not apprehensive about the doctors being able to modify their treatment at distance, without face to face contact.
- Their main expectation was that the device would provide better more continuous monitoring of the wound with less necessity for them to visit the clinic or hospital and reduce the need for hospital stays. However, loss of human contact with the medical team was seen as a disadvantage.
- They expected that the device would accelerate the healing process, and saw it as a means of preventing amputation, unfortunately often a long term outcome of DFU.
- They wish to remain independent, able to perform basic manipulations required by the device, thus it should be very simple to operate.

- They felt that carers (their partner, family or outside helpers), health visitors, their community nurse and GP should receive training in the use of the device. Patients with DFU are usually elderly and find it difficult to adapt to, to use and to remember how to use new technologies. They are often uneasy with using even relatively simple household devices. This must be considered in the design of the device so as to ensure that it will be used in real life. Likewise attention should be paid to the way in which its use is introduced as there may be a considerable learning period both for the patient, carers and nurses.

## VI. APPENDIX: FOCUS GROUP PATIENT QUESTIONNAIRE

### A. General questions:

- 1) When were you born?
- 2) What is your gender?
- 3) What is your domestic situation?
  - I live alone
  - I live with a partner
  - I live with my children
  - I live with both my partner and my children
  - I live with (one of) my parents
  - Other, namely
- 4) What is the highest schooling that you completed?
  - Junior high: less than 8 years of formal education (beginning at primary school)
  - High school: From 8 to 15 years of formal education
  - College: More than 15 years of formal education
- 5) Which of the following items do you use at home or at work?
  - Personal computer or Laptop
  - Cell phone
  - DVD player
  - Microwave
  - None of the above
- 6) Do you enjoy testing new electronic devices?
  - Yes
  - No
- 7) Do you have:
  - a cell phone : yes/no
  - a smartphone : yes/no
  - none

### B. Questions regarding physical characteristics and technical aspects of the device

- 1) If you have a Smartphone, do you expect that you, after having received instructions, will be able to use the application dedicated to the Swan-iCare device?
- 2) Your dressing will be connected to a box that contains the electronics needed to monitor and administer the treatment. How would you like to keep this box with you?
  - Attached around the leg
  - Attached around the waist

- In the sole of the shoe
  - n a shoulder strap
  - Don t know
- 3) How important for you are the following characteristics of the device. Please note from 1 to 5 each characteristic (5 being most important)
- Weight:
  - Comfort and wearability:
  - Size:
  - Vibration:
  - Autonomy (interval between battery charges or changes):
  - Interval between removing the waste from the exu-date canister:
- 4) For an optimal performance of the wearable device you may have to perform some actions at home by yourself. Which of the following actions you think that may be problematic?
- Replacement of the batteries (or recharge during the night): yes / no
  - Use a smartphone to communicate with a doctor: yes / no
  - Control your glucose level, (the results will be transmitted automatically via the smartphone linked to your wearable device): yes / no
  - Measure your body temperature once a day using a measurement device: yes / no
  - Enter data such as body temperature in the smart-phone: yes / no
  - Canister replacement: yes / no Remarks: If yes, please explain why this is a problem for you.

*C. Questions regarding possible impact of SWAN-iCare in daily life*

- 1) (If you live alone, go to the following question.) In case that you decide to use this device in the future, do you expect your housemates (e.g. partner and/or children) to support you?
- Yes
  - No
  - I dont know
- 2) How do you feel about the fact that the doctor is able to follow your wound remotely and that you are linked to the medical team permanently? (in terms of: feeling of control and emotional feeling/anxiety)
- 3) Would you have any concerns over your treatment being altered remotely, without any medical professional present (for example: infusion of some medicine to accelerate wound healing)?
- Yes
  - No
  - I dont know
- 4) What is the most important thing you would expect from this device:
- shortening of wound healing time

- reducing the pain due to your wound
  - both
  - other
- 5) If your doctor prescribed this device for you today, what advantage could it be to you?
- Shorter or no hospital stays
  - Less visits to clinic
  - all
- 6) What concerns do you have about the device?
- 7) Do you have any other comments, remarks, suggestions or questions regarding the SWAN-iCare wearable device?

*D. Questions regarding patients' foot wound.*

- 1) Do you currently have a foot wound that is being treated?
- 2) If so, how long has the current treatment been going on?
- 3) How many wounds have you been treated for within the past 5 years?
- 4) Have you ever had negative pressure wound treatment?

REFERENCES

- [1] King H , Aubert RE, Herman WH. Global burden of diabetes, 1995-2025: prevalence, numerical estimates, and projections. *Diabetes care.* 1998; 21:1414-1431.
- [2] Akthar S, Shaper N, Apelqvist J et al. A review of the Eurodiale studies: What lessons for diabetic foot care? *Current Diabetes Reports.* 2011; vol. 11. Nr. 4: 302-309.
- [3] IDF diabetes atlas, <http://www.idf.org/atlasmap/atlasmap>
- [4] Bartus CL, Margolis DJ. Reducing the incidence of foot ulceration and amputation in diabetes. *Current Diabetes Reports.* 2004; 4:413-418.
- [5] I. Markova. Les focus groups. in *Les methodes des sciences humaines*, S. Moscovici, F. Buschini eds. PUF 2003, pp.221-242
- [6] [Online] SWAN-iCare, [www.swan-icare.eu](http://www.swan-icare.eu).