



Social, Legal and Economic Implications for the Implementation of an Intelligent Wound Plaster in Outpatient Care

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Background: The care of chronic wounds is one of the core tasks of inpatient and outpatient care. The correct timing of changes has a significant impact on the positive course of wound healing. The VulnusMON project developed an intelligent wound plaster to determine the optimum time to change the plaster in hospital. Against the background of implementing the solution also in the outpatient sector, this article focuses on the following research questions: What is the legal framework for wound care in outpatient care? What are the differences in wound care between inpatient and outpatient care? What obstacles and barriers arise for the VulnusMON project when it is implemented in the outpatient sector? Can initial economic estimates be made for the transfer to the outpatient sector?

Method: Due to the complexity of the different research questions, a mixed method design was used. The qualitative part of the study includes both focus groups and expert interviews. As part of the quantitative analysis, a data set on outpatient wound care was analyzed ($n = 463$).

Results: In summary, it can be stated that the project VulnusMON and its intelligent wound plaster, which aims to determine the ideal time to change a wound plaster is viewed very positively by the professionals. However, there are a number of barriers that inhibit the potential transfer of the new digital solution to the outpatient setting. From an economic point of view, implementation in the outpatient sector makes sense, as travel times can be reduced. However, the study also points out important social implications, that pose several challenges for the actual transfer of the plaster to the outpatient sector.

Keywords: outpatient care, digital health, ELSI, wound management, health care

INTRODUCTION

The care of chronic wounds is one of the core tasks of inpatient and outpatient care. The correct timing of changes has a significant impact on the positive course of wound healing. Especially in the outpatient setting, infection control is a particular challenge because the environment does not provide the same hygienic conditions that exist in a hospital (Payne and Peache 2021). In addition, several studies show that the treatment of chronic wounds is a hereditary cost factor in the health system that is very often underestimated. At the same time, the studies point to an urgent need for action in the optimization of wound care so that, on the one hand, the quality of life of patients is

improved and, on the other hand, the costs in the area of wound care do not increase uncontrollably in the future (Olsson et al., 2019; Nussbaum et al., 2018; Bates 2020). Against this background three main factors can be identified through which better wound management can be achieved: Shortening the wound healing time, optimizing the frequency of dressing changes and reducing the prevention of wound infections. By achieving these goals, the quality of life of patients can be improved on the one hand and the costs in the context of wound care can be significantly reduced on the other (Lindholm and Searle 2016).

Around 3.4 million people living in Germany need care services. Three quarters of these are cared for at home. A large part of the care for the approximately 830,000 people in need of care is provided by the approximately 14,100 outpatient care services. This does not include people who only receive home care according to the Fifth Book of the German Social Code (SGB V). A further 820,000 people in need of care are cared for in the 14,500 nursing homes licensed under SGB XI (Federal Statistical Office, 2018, 2019). The quality of inpatient facilities and outpatient care is assessed and recorded through regular systematic evaluation. According to this, 6.6% of those in need of care in nursing homes and 7.3% in outpatient care suffer from chronic wounds, such as diabetic foot ulcers, decubitus ulcers or vascular leg ulcers (Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen, 2017).

Wound management is understood to be much more than just wound care. In fact, wound care is a part of wound management. The spectrum ranges from uniform diagnostics, the determination of wound types, healing and treatment, pain management to wound documentation. Experts from various medical professions are involved, including nurses with special training, the so-called wound managers or wound experts.

Effective wound management is an enormous challenge and is based on the complete documentation of the healing process by the wound experts and enables appropriate treatment adapted to the respective stage of the wound. Rapid intervention and transfer to safe treatment pathways increases the chances of accelerating wound healing, prevents complications, reduces pain and improves the quality of life of those affected. A distinction is made between acute and chronic wounds. In the case of the latter, both wound care and support for wound healing are considerably more complex. Wounds are described as chronic if they persist for more than eight weeks without therapy or do not heal within one to three months with the right therapy (Storck et al., 2019; Dissemond et al., 2017).

Against this background, it is clear that digital products can make a significant contribution to improving the quality of care in the health sector (Haggerty 2017; Alami et al., 2017; Kraus et al., 2021). However, it is also evident that the digital transformation in the health sector has started later than in other industries and has to overcome a number of barriers and acceptance problems (Herrmann et al., 2018). The evidence on digital transformation in care can be described as rather abstract at this point in time, because in the context of reviews, trends are usually paraphrased that have little empirical evidence, are based on expert opinions, or do not systematically correlate subjective assessments and objective

outcome effects (Johnson et al., 2019; Robert 2019). Studies that examine the perspectives of professional nurses on the use of digital technology in the work process focus in particular on the aspects of attitudes, acceptance and setting-specific readiness for technology. The results vary. While the spectrum of attitudes among caregivers ranges from skepticism to interest, more in-depth questions with a view to concrete obstacles to use reveal problems in completely different areas: For example, the technological infrastructures and possibilities for use are not always available, especially in elderly care facilities, and at the same time the age of the caregiver plays a central role (Papadopoulos et al., 2018; Rantanen et al., 2018; Coco et al., 2018; Hülsken-Giesler et al., 2019). In this context, ELSI research can make an important contribution to identifying problems and barriers already in the development process and to developing solution strategies for the further course of the project. (Goldenberg et al., 2019; Parker et al., 2019).

This paper describes part of the ELSI research, i.e., focusing on the social, legal and economic implications, using a concrete example. As part of the *VulnusMON* project, an intelligent wound plaster was developed that uses sensors as part of continuous monitoring to determine the optimal time when the plaster should be changed to optimize the wound healing process. For this purpose, parameters such as temperature, pH value, impedance and humidity are continuously measured and analyzed. The data from the local wound sensors are processed with further information and data from the patient's file. In this way, the wound healing process and the therapy are optimally supported. The patch was used in a German hospital as part of the project. The aim of this paper is to review the framework conditions that describe the potential use of the developed wound plaster in the ambulatory care sector. With this in mind, this paper describes the framework that characterizes the implementation of inpatient use in the outpatient sector. A practical implementation did not occur during the project period. Therefore, no conclusions about patient acceptance can be made at this time. For the ambulatory care sector there are some special features, so that a transfer and the associated requirements have to take certain aspects into account: Legal framework conditions that regulate the prescription of dressing materials, the place of use in the patient's household, which requires flexibility in standardized care processes, and a sometimes not yet high level of digitalization in the area of outpatient services, combined with a different form of work organization, present new challenges for the expansion of the *VulnusMON* project.

For the outpatient sector, there are two options, which are described below:

- Option I: Measurement and data transmission take place continuously in the patient's household. For this purpose, both the transmitter and receiver of the data are installed in the patient's household. The time of change is determined in real time.
- Option II: The transmission of data is done by a device that the outpatient care service carries with them. Accordingly, the care provider must be on site to transfer the data. The determination of the optimal time of change can therefore be delayed under certain circumstances.

TABLE 1 | Research design.

Topic		Method
Legal framework	Qualitative	Literature review
Differences in wound care between inpatient and outpatient		Focusgroups
Obstacles and barriers	Quantitative	Focusgroups
Economic		Data analysis

In order to develop targeted solution strategies in good time so that implementation in the outpatient sector can succeed, the overarching main question of the paper can be formulated as follows: What contribution can ELSI research make to support an implementation of a digital application in ambulatory care? This raises the following questions:

- What is the legal framework for wound care in outpatient care?
- What are the differences in wound care between inpatient and outpatient care?
- What obstacles and barriers arise for the VulnusMON project when it is implemented in the outpatient sector?
- Can initial economic estimates be made for transfer to the outpatient sector?

METHODS

Due to the complexity of the different research questions, it was decided to use a combination of different research methods. The methodological approach is based on the principles of mixed methods, in which both quantitative and qualitative research methods are used.

This raises the question of what goal is pursued by pursuing the research question with both quantitative and qualitative methods, if this results in a considerable additional expenditure of time and not infrequently also material and financial resources. There is agreement in the research landscape that the combination of the two approaches should balance out the respective strengths and weaknesses (Creswell 2014; Baur und Blasius 2014; Kelle 2014).

In this study, too, the main question is therefore the added value of combining methods to answer the question. If one orients oneself to the five basic functions (validation, complementarity, initiation, development and extension) to which a mixed methods approach can be assigned, the function of extension is identified for the present expertise. This function is characterized by the fact that the quantitative and qualitative approach refer to two different areas in connection with one object (Schreier and Odağ). The subject matter is ambulatory wound care, the quantitative approach refers to economic issues while the qualitative approach refers to the experiences and evaluations by the nursing staff. This research design can be called Convergent Parallel Mixed Methods (Creswell 2014) and can be presented as displayed in **Table 1**.

In the first step of the study, a literature review was conducted, which took into account both the state of the art in outpatient

wound care and the legal basis in Germany. The qualitative part of the study includes focus groups as well as expert interviews. A total of two focus groups were conducted. In the first focus group, a special focus was placed on outpatient wound care and the associated challenges for the wound patch. The focus group consisted of eight wound experts who work in ambulatory care. The second focus group dealt with general questions about digitalization in the outpatient care sector. This focus group consisted of management and nursing staff as well as people from the technical sector. Furthermore, five expert interviews were conducted with managers of outpatient care. The content of the focus groups was as follows: At the beginning, the process of wound care in outpatient wound care was addressed (only in focus group 1); in the further course, the impact of digitalization on the outpatient sector was discussed. In the last part, the digital solution was presented in order to discuss questions of potential practicability and acceptance. The expert interviews included the same thematic aspects and served to sharpen the content of the results.

The instrument of qualitative content analysis was chosen as the evaluation method. It stands as an evaluation method for data that accrued within the framework of qualitative research projects and is characterized by the fact that it is also able to handle large data volumes and to structure them through a rule-guided procedure (Mayring and Fenzl 2014). Within the framework of the quantitative analysis, a data set on outpatient wound care of an outpatient nursing service was analyzed. Descriptive methods were used for the analysis, all calculations were carried out with the statistical software SPSS.

RESULTS

The Legal Framework for Outpatient Wound Care

Successful treatment of chronic wounds often takes place with the involvement of several medical professional groups to ensure proper wound care. The treatment usually extends over a longer period of time. Professional assessment and treatment of wounds is crucial for wound healing and can be carried out by doctors as well as by qualified nursing staff, the so-called wound managers. The doctor is initially responsible for diagnosis. When deciding on therapy, which is also part of his or her area of responsibility, he or she decides whether and to what extent treatment care activities should be delegated to nursing staff (Reibnitz and Skowronsky 2018).

Should it prove medically necessary from the doctor's point of view, he or she can refer the patient to a specialist or even to hospital for inpatient treatment. Wounds are treated with dressings specially developed for wound care, which can be redeemed by a prescription from the doctor at a pharmacy and a medical supply store. As with medicines, the statutory co-payment applies here for each dressing prescribed.

The dressings are changed at a prescribed interval according to the instructions of the attending physician. The doctor can issue a prescription for the outpatient nursing service. As a rule, the wound managers are responsible here, whose goal is to promote the quality of life of the affected person through appropriate wound care, to support wound healing and to prevent a recurrence of the wound. If necessary, wound managers can also instruct patients to take over wound care independently in the long term. Dressing changes by an ambulatory care service are a service of home health care and are subject to reimbursement. In general, the expenses for the necessary measures for wound care are prescriptive according to §31 SGB V and are covered by the health insurance funds. The professional wound and photo documentation is part of the nursing documentation and therefore falls under the responsibility of the wound managers. The physician's task is to document the course of treatment in the medical records (Deutsches Netzwerk fü; Reibnitz und Skowronsky 2018).

In order to successfully carry out wound healing, further medical products, so-called aids, may be necessary in certain cases. Aids to support the healing process of wounds can also be prescribed by the doctor. These can be obtained from a medical supply store.

When prescribing services and products, the doctor is bound by the principle of economic efficiency according to §12 Para. One SGB V, i.e., the services must be sufficient, appropriate and economical and must not exceed what is necessary. For this reason, not all available services and products are reimbursable for wound treatment and can only be reimbursed after prior individual approval by the health insurance fund. If they are not included in the catalog of benefits of the health insurance funds, they must be financed by the patients themselves.

Outpatient wound care is subject to specific courses of action and legal framework conditions that must be taken into account for the appropriate care of patients, but also for the protection of service providers. The legal and contractual stipulations in the Social Code Book XI and Social Code Book V define the range of services of outpatient care that are available in Germany for the management of problem situations in connection with illness and the need for care in the home environment. The Federal Joint Committee has expanded the specifications for the care of patients with chronic and difficult-to-heal wounds in the area of home care in 2019. According to this, the care of chronic and difficult-to-heal wounds should primarily take place in the household of the insured person or, according to §2, in other suitable places where the insured person frequently spends time.

If this is not likely to be possible in the insured person's home due to the complexity of the wound care or the circumstances in the home, the wound care should then take place in specialized facilities. However, this must be evident

from the regulation. For the care of chronic and difficult-to-heal wounds, the service is to be prescribed according to the procedures for no. 31a. According to §3, every home nursing measure requires a medical prescription. The service providers who carry out the measures within the framework of home nursing care are first bound by the prescription and then by it if approval is given.

According to §7, the care provider reports to the treating contractual doctor on changes in the home care situation, in particular home nursing care, or upon request by the doctor, if necessary also by transmitting extracts from the care documentation. The doctor decides on the necessary measures resulting from this (Gemeinsamer Bundesausschuss 2019). Accordingly, the legal framework clearly specifies that the prescription for treatment is made by the general practitioner. For the VulnusMon project, this means that, especially in the outpatient sector, GPs must be included in the supply chain and they must also have the necessary infrastructure.

Differences in Wound Care Between Inpatient and Outpatient Care Settings

In the focus group discussion, the ordinary process of wound care is discussed. The usual care process is as follows: A wound expert goes out to the patient and looks at the wound and takes a photo. The expert then contacts the primary care physician because he or she must issue the prescription. The wound expert makes a recommendation on how to treat the wound. The doctor then makes the decision on how to treat. Ideally, there is subsequently regular contact with the family doctor's office with photo documentation of the wound healing:

“Normally, if the wound deteriorates, contact is made with the primary care physician or the physician specifies a time period where the status of the wound should be reported. If there are changes or deterioration, an alternative treatment method can be discussed.”

Most wounds that occur are pressure ulcer treatments, leg ulcers, unhealed surgical wounds, and wounds related to falls. In this regard, the wound managers note that there is a specific treatment method for each wound. This also means that there are different dressing materials and certain materials are contraindicated for certain wounds. This results in a wide range of patients with different ages. In general, the average age of patients with wound care only tends to be lower than in the outpatient setting. There are many patients with wound healing disorders after surgery. As already described above, these are usually patients for whom only the wound is treated and who, after healing, are no longer part of the nursing service's clientele. Regarding the task of wound experts, however, it must be noted that their duties do not exclusively include the care of wounds. The nurse must also perform the other tasks of care. In everyday life, it can always be the case that other nursing staff who are not so well versed in wound care consult the wound experts.

The group clearly states that there is no such thing as “typical wound care” in outpatient care. The care processes are much less

standardized here than in inpatient care, because the nurses have to adapt to the home situation and the associated environment.

Wound care in the outpatient setting is very different from care in the inpatient setting. There is significantly less time available: For example, there are wound irrigation solutions that are supposed to soak in for 15 min. In outpatient care, there is no time for this. On average, dressing changes in outpatient care take 8 min. In this situation, the nurse must therefore assess whether to reduce the exposure time and thus accept that the solution will not achieve its full effect, or whether the specified time will not be adhered to, which can, however, result in the entire time and tour schedule being disrupted. In general, it is noted that the time allowance is a major problem: if the preparation time of the workplace, the careful disinfection and the changing into appropriate protective clothing are included, there is effectively very little time left for the actual assessment, documentation, and care of the wound.

There are also significant fluctuations in the amount of wound care that is provided to patients: There are times when there are very few patients with wounds to care for, but then it can also happen that five new patients with wound care are added in one fell swoop. Very often it is the case that only the wound needs to be treated and no further nursing care is provided. Typical examples of this are wound care after operations or secondary wound healing. For the nursing staff, this means that they must constantly adapt to new situations and environments.

Regarding the actual care process, the focus group notes that there are many differences compared to wound care in the inpatient area. In the inpatient setting, the entire process can be observed with better accuracy, because there is constant contact and exchange with the patients. In outpatient care, for example, dressing changes are prescribed three times a week, and the patient is then visited on these days. However, nurses often are unaware of what is happening on the other days. If the patient is unable to report if something is wrong with the dressing, the wound healing process can be adversely affected. Such problems and difficulties can occur repeatedly. Therefore, outpatient nurses must be prepared to react very flexibly.

The actual work process is also influenced by the situation on site. It very often happens that the hygienic conditions are not the same as in the hospital:

“That doesn’t even mean that households are particularly dirty. Of course, that happens, too, but that’s a completely different issue. There are just things that are just different than in the hospital. There isn’t always a closet where we can store the material. In many households, there are also pets, so you have to pay special attention. In inpatient care, if you don’t have enough material or need something else, you can go to the material storage. In outpatient care, however, you have to make do with what’s on hand. That’s where improvisation is often needed.”

The group goes on to say that in many cases the workspace is significantly limited, and one must improvise because the work

surface is much smaller than in the hospital. In addition, the lighting conditions are not always optimal.

A very central distinction from inpatient care is the role of the caregiver, which is taken in outpatient care:

“The role of the nurse is also different. You are a guest in someone’s home and if a patient wants something done a certain way, even though it doesn’t make sense from a professional point of view, you do it the way he or she wants it done. That may sound more dramatic than it is. Generally, there are few problems, but you have to keep reminding yourself that you are invading their privacy much more intensively than you would in inpatient care.”

This aspect applies not only to wound care, but to the entire nursing process and is very closely linked to adherence to specific times. The group states that a steady routine of care is very important for many patients:

“Many patients are used to fixed times when we visit them. They adjust to this and set up their daily routine that way. If we then come at other times because there is a postponement, because an emergency has come up or the tour had to be changed, some become impatient quickly.”

In the focus group it emerged that in several cases there are problems with the communication with primary care physicians. Although all participants in the focus group have further training as wound managers, in certain cases they feel that they are not taken seriously in the discussion with the primary care physician when the treatment process is coordinated:

“Doctors never discuss with us at eye level, but many doctors have no idea about wound care.”

Problems always arise when primary care physicians prescribe treatment that is out of date and not conducive to the wound healing process. In such a situation, the wound expert is allowed to say if he or she does not agree with a treatment and can refuse to perform it. A continuing education program ensures that wound experts are always aware of the latest advances in care. They usually have a significant knowledge advantage over primary care physicians, although some practices now have wound experts. Additionally, a very common problem is prescribing high-cost materials because it impacts the primary care practice’s budgeting. In general, one has to be much more economical with materials in outpatient care because much less is prescribed and one always has to obtain a new prescription from the practice, combined with the difficulties just described. Very often, these disputes are fought out at the expense of the patients, because they do not receive the most effective care:

“In one specific case, a doctor refused to prescribe dressing material, this was all documented and the

wound actually worsened considerably. It was then suggested to the practice that the patient should be transferred to a wound outpatient clinic, and that ultimately happened.”

Relatives also play a very important role in the outpatient care setting. This does not only apply to wound care, but it also rather refers to the entire care process. Sometimes relatives make a lot of effort, but sometimes they don't. For example, they apply ointments that don't help at all and sometimes even contribute to worsening the wound. This is often well-intentioned on behalf of the relatives because they want to support the nursing staff in their work. Very often, however, the exact opposite is achieved, as the wound healing process is halted. In this situation, it is very difficult for nurses to find the correct words so as not to offend the relatives. Some relatives also want to observe and document every step of the process. The nursing staff consider this to be very disturbing, because they cannot concentrate on their work and are distracted:

“It has also happened several times that I have ordered a relative out of the room because he was disturbing too much. Of course, he is offended at first, but you have to find the right words and make it clear that you can't do your job properly like that.”

Obstacles and Barriers

The focus group agrees that digitization has not yet made much of an impact on outpatient care. The care documentation that is carried out at the care service, for example, is still done handwritten. The group knows that it is already different at other services. They state that in a few years, complete documentation will certainly be done digitally. However, the group cannot judge when a digital transition will take place. However, a conversion to digital documentation requires a lot of time and requires a complete reorganization in many processes. Above all, the documentation is viewed very critically:

“A digital care plan is very inflexible, you can't react as flexibly to changes as you can with handwritten documentation. It lacks all the individuality of the patients. It is much too rigid. Wound documentation in particular has to happen very individually. I have great doubts as to whether digital documentation can reflect this individuality.”

However, some processes are already being done digitally today. Tour planning is already done digitally today. A central PC creates the plan, which is then transferred to the nurse's cell phone. In addition, the photo function of the cell phone is used for documentation, especially for wound care, because this allows the healing process to be recorded at regular intervals:

“In rare cases, it even happens that the doctors have the wound history sent to them via WhatsApp. They can then respond with their prescriptions and adjust the

material if necessary. However, this does not happen very often.”

The focus group finds it very difficult to make a general assessment of whether digitization has a positive or negative impact on outpatient care. In many cases, data protection hinders work in outpatient care (e.g., fetching prescriptions). A lot depends on how user-friendly the programs are. The group describes the impression that many functions are not always useful. In addition, there are also fears and doubts among the patients:

“On the street, everyone is just walking around with a cell phone. Now the nurses also come with cell phones and start clicking around.”

In the further course of the focus group discussion, the VulnusMon project, i.e., the intelligent wound plaster, is presented to the participants and it is discussed with them how sensible it is to use it in outpatient care. The group notes that many patients find digital devices very impersonal. There are also doubts as to whether patients agree to their data being transmitted:

“Many patients see this as an intrusion on their autonomy and do not want to relinquish control over their bodies in this way. They will certainly feel a kind of surveillance.”

Another problem is that cell phones already have many gaps in coverage in many regions. Whether smooth data transmission is guaranteed in all households is highly doubted. If a Wi-Fi connection has to be available in the household, there are further problems, because at the present time many people do not yet have Wi-Fi in their homes and do not intend to acquire this technology. This is especially true for senior households. In addition, the fixed daily structure of the patients mentioned above is seen as a possible barrier to implementation:

“The patient needs communication. It is difficult not to be able to tell the patient exactly when you will be back. These fixed appointments play an important role.”

The experts further note that the patient's condition plays an important role in whether such a system can be used. There are very often restless patients who move around a lot, so the dressing can slip due to scratching or movement. The group is sure that these effects will certainly influence the measurement. On size and material, the experts note that there are very different sized wounds. And on dressing material, it has already been said above that there is different material for certain types of wounds:

“One for all does not work!”

Many wounds are also dressed with compression, so the plaster must also be able to withstand pressure and must not negatively affect the wound in the process. This aspect must

TABLE 2 | Total number of patients and patients with wound care.

	Number	Share
Total number of patients	463	100%
Patients with wound care	75	16.2%
Patients ONLY with wound care	21	4.5%

definitely be taken into account in further development, as the wound often remains unseen for several days, especially in the outpatient area. If the transmission does not work and the sensor causes unnecessary pressure points, this can have serious consequences for the wound healing process.

Determining the ideal time to change dressings is seen as very useful, although it is associated with difficulties when implemented in outpatient care. However, it would be conceivable for the data to go directly to the primary care physician. This relieves the nursing service and reduces errors in the transmission of information.

Economic Estimations for Outpatient Wound Care

During the expert interviews with managers of outpatient care services, the aspect of the economic dimension was addressed:

“It can be assumed that, from an economic point of view, pure wound care is not lucrative for the nursing service. You travel to the patient every other day to treat the wound, regardless of whether the plaster needs to be changed or not. The nurse spends a lot of time in the car, which cannot be billed.”

This statement will be verified in the following using quantitative methods. For this purpose, the patient data set of the nursing service involved in the project will be used. The data set contains all patients who received nursing care in 2017. Accordingly, the project does not collect its own data material, but rather concentrates on the analysis of secondary data material. The data set includes information on gender, age, type of care, and duration of care.

In 2017, a total of 463 patients were cared for by the outpatient nursing service (Table 2). Of these, 75 patients received wound care, which corresponds to a share of 16.2%. An analysis of the data shows that a large proportion of patients who receive wound care also receive other nursing services from the nursing service. This is the case for 54 patients, consequently 21 patients received only wound care from the ambulatory care service in 2017. More than 70% of the patients who receive wound treatment also receive other nursing care. The proportion of patients who are cared for exclusively by the outpatient nursing service for wound care is thus just under five percent (4.5%).

If we look at the age structure of the patients, the following picture emerges: The average age of patients receiving only wound care is 69.8 years (SD 15.88). For patients who receive other nursing services in addition to wound care, the value is 78.9 years (SD 11.01). The difference is significant ($t(63) = 2.710$,

TABLE 3 | Age structure of the patients.

Age	Patients with wound care (%)	Patients only with wound care (%)
Under 60	7	8
60–69 years	14	19
70–79 years	19	24
80 years and older	60	49

TABLE 4 | Average duration of care services in minutes.

	Avg	Min	Max
Total number of patients	10.9	5.1	20
Patients only with wound care	12.5	6.6	20
Patients with wound care	10.2	5.1	18.3

$p = 0.009$). Table 3 shows how the proportions are distributed within the age groups.

The age structure of all patients with wound care shows that the majority of patients can be attributed to the group of the very old (80 years and older): With 60%, clearly more than every second patient with wound care is 80 years and older. One fifth of the patients form the group of persons who are between 70 and 79 years (19%). With decreasing age, the proportion becomes smaller: 14% of the patients can be assigned to the age group 60–69 years. Only 7% of the patients are younger than 60 years. If one looks at the age structure of patients for whom only wound care is performed, the assumption that these patients are younger than patients for whom additional nursing services are performed is confirmed: The proportion of persons younger than 60 years increases by one percentage point. The increase in the next age group is already clearer: with 19%, the share value in the age group 60–69 years is clearly higher than in the patients for whom a nursing measure is also carried out in addition to wound care. To assess the correlation Cramer V was calculated. There is a medium correlation between the variables age group and wound care ($V = 0.396$).

In the following, it will be shown how long an intervention at the patient’s home usually takes. Here, a differentiation is made between patients with additional nursing care and pure wound care.

From Table 4 it can be deduced that there is a slight difference in the average duration of care: While the average duration of care for patients with only wound care is 12.5 min, it is slightly shorter at 10.2 min for patients who receive care in addition to wound care. At the same time, both types of care show a very wide range. If we look at wound care alone, the minimum is 6.6 min, compared to a maximum of 20 min. The difference is significant ($t(61) = -2.806, p = 0.007$).

In a further step, it will now be examined which economic statements can be made about outpatient wound care on the basis of the patient data. For this purpose, the following hypothesis is formulated: H_1 : Pure wound care is not effective for the nursing service from an economic point of view.

The following key figures will be used for this purpose:

TABLE 5 | Economic framework for outpatient wound care.

22 Patients with wound care only			
Number of deployments	767		
Revenue per deployment	14.19 €		
Total revenue	14.19 € × 767	10,884 €	
Total operating times (without route)	158		
Travel times in hours	128		
Total effort in hours	286		
Hourly rate (incl. Material and overhead costs)	45 €		
Total cost	45 € × 286	12,872 €	
Difference	Defizit	1,988 €	

- Number of patients
- Number of operations
- Revenue per operation and total
- Total operating times in hours
- Total travel time in hours
- Total costs

As seen in **Table 5**, it can be concluded that the pure care of wounds in outpatient care without additional nursing services is associated with deficits for the nursing service presented here. These deficits can be explained above all by the high time expenditure of travel: In one year, 767 missions were made in which only wound care was administered to the patient. This corresponds to a time expenditure of 286 h. Of these, 128 h were spent in the car alone, which corresponds to a share of almost 45%. The driving time is not billable for the nursing service, so a large part of the working time incurred is not billable for the nursing service via the health insurance. The other 55% of the total time is spent on wound care in the patient's home. Here, one service is remunerated at €14.19. If the costs for the nursing service are calculated using an hourly rate of €45, which includes material and overhead costs in addition to personnel costs, this results in a total deficit of almost €2,000 per year. The results clearly show that the hypothesis formulated at the beginning is agreed with.

Against the background of this calculation, it becomes clear that the introduction of the digital wound plaster makes sense from an economic point of view. The area of wound care has so far been running at a deficit. With the determination of the optimal time for changing the plaster, travel times can be reduced, as it can be assumed that the number of interventions will also be reduced. This calculation assumes that the wound healing process is better with the use of the digital wound plaster than with conventional wound treatment.

DISCUSSION

In this section, the identified barriers are now discussed with possible solutions for a successful implementation in the outpatient setting: The central person in outpatient care in wound care is the wound manager, who contacts the general practitioner after inspecting the wound. He makes suggestions

for treatment, the final decision is made by the general practitioner. The general practitioner then issues the prescription for the wound treatment. This process does not run smoothly in practice. In many cases, communication with the general practitioner is not on an equal footing, so that the wound manager's recommendation is not always put into practice. The GPs are not always up to date with the latest developments in wound treatment. In addition, low budgeting for reimbursement often leads to treatment steps not being prescribed in a timely manner. For this reason, a follow-up project is recommended in which the inpatient solution is transferred to the outpatient sector. In this follow-up project, a network of nursing services, general practitioners and specialists should be created, in which a joint training can be implemented and evaluated.

It should also be noted that there is a specific treatment method for each type of wound, combined with the correspondingly different dressing materials. The sensors must therefore be applied to different dressing materials. An alternative would be to separate the sensors and the plaster material so that both can be combined individually for the corresponding wound type. A number of wounds are treated with compression bandages that apply pressure to the wound. The material of the sensors must be chosen so flexibly that no pressure points can develop.

In outpatient care, wound treatments often occur where only the wound is treated, and no other nursing services are performed. Very often, the patients are younger on average than the other patients in outpatient care. Many elderly people do not yet have a Wi-Fi-connection in the house. A mobile solution that the care service brings with them is less suitable because the data cannot be passed on continuously. As part of a follow-up project, the households should be equipped with the technical infrastructure. In the course of the increasing digitalization of households, however, this barrier will become smaller in the near future.

The work processes in wound care in outpatient care differ significantly from the processes in inpatient care: The situation alone of being a guest in the patient's household is a challenge for the nursing staff. Furthermore, the working conditions (cleanliness, hygiene, material, workplace) are not at the same level as in inpatient wound care. The use requires a rethinking in the entire area of outpatient care: This applies to the operative level as well as to the planning and management level. When using the digital solution, the nursing staff must be able to react flexibly when a dressing change is indicated.

In general, the effects of digitalization on the field of outpatient care are perceived as rather difficult: Experiences with digital documentation have not provided any relief; rather, it has not been able to map the complexity and individuality in outpatient care. At the same time, it is also evident that there has been very little experience with digital products in outpatient care so far. The overall goal of the *VulnusMON* project is positively received, but the high degree of digitalization and further barriers (e.g., plaster must be able to treat different types and sizes of wounds) ensure that the use of the digital wound plaster in care is assessed as rather unlikely

at the present time. The effectiveness of the application must be proven by clinical studies. This will make the benefits more transparent for nursing staff and patients. Furthermore, a participatory method should be chosen within the framework of a research project for implementation in the outpatient sector, so that nursing staff and doctors' practices are involved in the development and adaptation process at an early stage.

In summary, the integration of ELSI questions in the context of an exploratory study turns out to be very useful. Thus, barriers and obstacles could be identified at a very early stage, which can be taken into account in further project planning. It has been shown, for example, that implementation will lead to major changes in established work processes. As a result, the qualification process, which is absolutely necessary for successful implementation, should include not only nursing staff but also physicians and patients, because their routines will also change significantly. At the same time, it shows that it makes a lot of sense to look at all aspects of ELSI research together in order to point out apparent contradictions and to develop measures in time that can resolve the contradictions. The example of the intelligent wound plaster, for example, has shown that implementation makes sense from an economic point of view, but that social

implications present a number of challenges that need to be addressed in the actual implementation phase.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

AUTHOR CONTRIBUTIONS

PE was responsible for the research design. PE was also responsible for data collection and analysis. The writing of the manuscript was done in collaboration between PE and AK.

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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