Design of a Machine Learning System for Prediction of Chronic Wound Management Decisions

Abstract. Chronic wounds affect 6.5 million Americans, are complex conditions to manage and cost $28-$32 billion annually. Although digital solutions exist for non-expert clinicians to accurately segment tissues, analyze affected tissues or efficiently document their wound assessment results, there exists a lack of decision support for non-expert clinicians who usually provide most wound assessments and care decisions at the point of care (POC). We designed a machine learning (ML) system that can accurately predict wound care decisions based on labeled wound image data. The care decisions we predict are based on guidelines for standard wound care and are labeled as: continue the treatment, request a change in treatment, or refer patient to a specialist. In this paper, we demonstrate how our final ML solution using XGboost (XGB) algorithm achieved on average an overall performance of F-1 =.782 using labels given by an expert and a novice decision maker. The key contribution of our research lies in the ability of the ML artifact to use only those wound features (predictors) that require less expertise for novice users when examining wounds to make standard of care decisions (predictions).

Keywords: Point-of-care decision, Machine learning, design science, chronic wounds, non-expert clinicians

1 Introduction

Chronic wounds (also known as chronic ulcers) affect 6.5 million Americans [1], are complex conditions to manage [2], and cost $28-$32 billion annually [3]. Yet, the majority of patients with chronic wounds do not have access to evidence-based wound care services or certified wound clinicians [4]. As a result most wound assessments and care decisions are provided by non-expert clinicians (with no wound specialization training) who have limited chronic wound treatment expertise [5]. This lack of expertise results in uncertainty during wound care decision-making causing inaccurate treatments. If inaccurately diagnosed or inappropriately treated [6], wound healing may be delayed resulting in amputations [7], limited quality of life and even death [8]. Thus, patients must receive appropriate wound care to maintain normal healing process [9]. Although narrative wound care guidelines exist to support these clinicians [10-12], non-adherence to these guidelines is reported recurrently [13]. There is the burden of finding the right procedure for the right patients on the user of these guidelines. This burden becomes even heavier with having to cope with narrative descriptions that may not align with their current expertise and knowledge. However, there exist opportunities for using ML to support POC wound care decisions which is the focus of current paper.

In this paper we demonstrate the design and development of a ML solution that is envisioned for a smartphone clinical decision support system (CDSS) app. The envisioned CDSS app will take advantage of this ML solution that can predict decisions only by taking raw wound images using phone camera. These decisions are generalizable to contexts where both experts and novices make wound care decisions.

2 Background: Challenges and opportunities for chronic wound management

2.1 Accurate diagnosis and treatment

Chronic wounds are characterized as diabetic foot ulcers (DFUs), pressure ulcers (PUs), venous ulcers (VUs), and arterial ulcers (AUs) and surgical wounds. Each wound type has different assessment and management procedures. Despite the abundance of published chronic wound management studies (e.g., clinical trials and decision guidelines) on how to treat these wounds, non-expert clinicians delivering wound care still have major clinical uncertainties as to which decision to make when it comes to a particular wound [14]. This often leads to undesirable wound care outcomes [15], patients being harmed [16] and waste of healthcare resources [17]. Hence research is required to develop alternative decision support tools, such as digital wound care support using ML solutions, that enhance wound healing [18] and reduce costs [19].

2.2 Consistent and collaborative decision-making

Wound care is known to lack standardization within and across institutions and among specialists [20]. Although models of collaborative reorganization and integrated care have been proposed [20], there still is a great need for more highly trained providers in the wound care community (registered and visiting nurses, wound practitioners and experts, vascular, podiatric and plastic surgeons). In the wound care community non-expert clinicians deliver most of the wound care, e.g. changing wound dressings and collecting wound measurements. Their assessment often requires judgment and decision-making in complex, challenging and uncertain circumstances [21]. Such a complexity in a dynamic wound care context [22] creates uncertainty for these non-expert clinician decision makers [23]. Uncertainty can also derive from lack of relevant wound care knowledge and expertise [22]. To help non-expert clinicians there should be alternative solutions such as digital support tools that simulate standard wound care guidelines for more consistent decision-making [24].

Non-expert clinicians may draw on their intuition to guide their judgments and decision-making by association with experience and expertise [22] which then increase their uncertainty. Hence, the digital support tool must use a generalizable solution based on standard wound care that is applicable to contexts where both expert and non-expert clinicians treat patients. Avoidance of inconsistent decision making across the wound care community will promote high-quality wound care and protect chronic wound patients.

2.3 ML practices for chronic wound management

Several ML studies have attempted to provide digital chronic wound care support for non-expert clinicians. For example, one study [25] proposed a telemedicine tissue segmentation (granulation, necrotic, slough) using linear discriminant analysis (LDA) to assist the clinicians to make better chronic wounds diagnostic decisions. Their model was trained on 60 digital images and used wound tissues in color images of both pressure and diabetic ulcers. When evaluated on ground truth images labeled by experts, the model could classify the tissue types with overall accuracy of 91.45 %. Another study [26] used information collected during routine care in outpatient wound care centers and developed a digital predictive ML model for delayed wound healing. A total of 180,696 patient wounds were collected at 68 outpatient centers. The data from first and second wound assessments was used to construct predictors of delayed wound healing. The model achieved an area under the curve (AUC) of 0.842 for the delayed healing outcome. For wound assessment and efficient documentation, we found one recent study [27] that developed a smart-glass based POC solution using DSR methodology. Although their study demonstrated through user experiment a unique approach for efficient wound documentation, it did not utilize ML prediction to support non-expert decision making.

2.4 Uniqueness of the current study

Our study aims to design a ML solution artifact that can predict wound care decisions based on labeled wound image data. We use visual and descriptive features from the image as predictors and care decisions as target labels. The decisions we predict are based on standard wound care guidelines and are labeled as: continue with the current treatment (D1), request non-urgent change in treatment from a wound specialist (D2), or refer patient to a wound specialist (D3). Our ML solution artifact is unique in several ways: (a) It predicts care decisions for all main types of chronic wounds (DFUs, Pus, VUs, AUs and surgical), (b) It is trained and tested on a diverse collection of labeled image datasets (local hospital collection and publicly available web collection), (c) It has a knowledge base of predictors that are extracted from a collection of wound care guidelines, and (c) It uses a decision pathway that mitigates inconsistent decision labels for the training image datasets that lack information about current treatments for each image.

2.5 Use scenario addressed by the artifact

The design process is inspired by the scenario where a wound non-expert clinician, who treats patients for various conditions within a clinical or non-clinical setting, encounters a patient with a lower extremity (LE) chronic wound. If this is a new undocumented LE chronic wound with no current treatment plan, this non-expert clinician will refer the patient to a wound specialist for initial treatments and timely plan of care (2-week/4-week follow-ups). Due to the patient’s immobility, transportation time and costs, and lack of access to wound care clinics, regularly visiting a wound expert clinic becomes challenging. As a result, these patients will continue receiving their routine wound care (according to their current treatment prescribed by the wound specialist) through local non-expert clinicians. This routine wound care includes dressing changes, contacting the expert for type of dressing and replacement products (if any changes), reassessing and documenting the wound measurements (depths, height and width), controlling infections using antibiotics and providing non-sharp debridement.

The non-expert clinician must be able to identify healing wounds from those that require non-urgent change of current treatment and most importantly wounds that must be urgently referred to the wound specialist for surgical closure, debridement or surgical referral. The quality of these decisions will determine the progress of patient's wound and wound care outcomes. To address this use scenario, we ask the following design questions: ***How can we design a ML system artifact that can accurately predict standard of care decisions for LE chronic wounds?*** *Can this* ***ML system artifact*** *produce consistent decisions using labels given by expert and novice decision makers?*

3 Research methodology and design process

When adherence to clinical guidelines is ignored, the treatment procedures clinicians (wound experts and non-experts) follow may differ considerably. This results in inconsistent decision-making across the chronic wound care community (i.e., some clinicians may be aggressive about debriding the wound, while others may be less concerned about regular debridement). A ML system that can provide generalizable decisions that follow the standard of care can address this issue. To do so, we defined the following design requirements (DR) for our ML artifact that predicts sensitive chronic wound management decisions: *DR (1)*: The knowledge base for ML system artifact to predict wound care decisions should include the common features recommended by standard wound care practices. *DR (2)*: The ML system artifact design should include procedures that ensure the accuracy and consistency of expert and non-experts' decisions when treating chronic wound patients. The process for designing the ML system artifact was followed by the design science methodology [28] and went through two phases and two design cycles as described below.

4 Design phase one- Developing standard of care knowledge artifact for wound care

4.1 Cycle 1: Understand the domain, develop and evaluate knowledge base

We began by developing the wound care knowledge base using requirements that we identified through (1) literature and (2) expert interviews as described below.
Literature. We collected information about visual characteristics of all the chronic wounds from published articles and Wound Union Wound Healing Society clinical guideline [29]. The main inclusion criteria for both published articles and guidelines were wound types and their diagnostic features (wound shape, etiology, tissue colors,

etc.). Features were extracted for each wound and stored in spreadsheets. These features were then compared to each other by their visual and non-visual (patient history data, smell, warmth, etc.) characteristics. We also compared their terminologies since some guidelines used different names for similar wound features. This step was necessary to build an accurate wound feature table and then to classify wound features by their common terminologies. We reviewed and compared several wound assessment tools (Braden scale [30], Pressure Ulcer Scale for Healing (PUSH) [31], Wound, Ischemia and Foot Infection (WIfI) [32] and Photographic Wound Assessment Tool (PWAT) [33]) to find the one that uses more accurate yet visual features for our wound feature table. We selected PWAT, a validated visual wound assessment tool, as it was the only wound assessment tool designed to work with wound photos. The other tools in the literature were designed for bedside assessment and require inputs beyond what can be gleaned from an image including infection status and blood flow of the wound. PWAT has eight sub-scores each of which receives a score from 0 to 4 (0 represents conditions observed in a healing wound and 4 represents conditions observed in wounds that are not healing or degrading). The total score of the PWAT adds up to 32 which represents a wound in a very severe condition [33].

Wound expert interviews. Before the interviews, we selectively resampled two sets of wound images from two sources for which we had IRB approval. One set had 29 images (with high, middle and low PWAT scores) from chronic wound image repository of a local hospital. The second set had 6 images with doctors' notes and decisions from our ongoing data collection at a local hospital.

We conducted two rounds of semi-structured interviews with a dually credentialed podiatric surgeon/vascular nurse practitioner and a plastic surgeon from an academic medical center in the northeast (4 total interviews). Each interview took 1-2 hours and was video recorded and transcribed.

At the beginning of each interview, wound experts were given clear explanations about the goals of the project. We asked our experts what a standard assessment tool would ideally include, how they assess a wound visually, and what suggestions they have for project improvement. We also requested our experts to visually assess only 15 images from set one (experts annotated all 29 images with decision labels) and give additional expert information. In the second round of interviews, we used the same wound images but asked both experts to visually assess and explain their assessment procedure for wound depths, underlying tissues and other clinical characteristics in detail. Transcriptions and videos were analyzed by one of the authors, and new findings were added to the wound feature table.

Developing decision rules. The review of literature, analysis of clinical guidelines and expert interviews helped us identify critical wound features required for assessing a chronic wound. These features were used to design IF-THEN rules that capture chronic wound conditions based on location and visual descriptors [34]. These rules were tested using a decision table to solve for overlapping rules.

Evaluation of the decision rules. We tested our decision rules on 14 remaining images in the set one annotated by the two wound experts (see Fig. 1 for an example of wound image). The goal was to check each of the assessment rules to see how visual features are presented and verify them when necessary. Out of 14 total instances, decision rules could not accurately assess two wound types (Diabetic and Venous ulcer) due to imprecise location and history features (85.7 % accuracy). Each corresponding rule and the experts' descriptions for the wound images were analyzed and location information and patient history data were added based on guidelines. Modifications and changes were made to the rest of the rules to enhance the location rule.

4.2 Cycle 2- Rethinking the domain knowledge

In the second cycle we revisited the wound knowledge base and added extra features from a total of 14 guidelines to make the decision rules more comprehensive. The total predictive features from our wound feature table were raised to sixty-one visual and non-visual features. We used a decision table to find the best matching rules with no overlap (see Fig 1 for example of a decision rule). This resulted in thirty-nine decision rules. These rules were validated further using 4 new wound images and their corresponding clinicians' notes extracted from the wound clinic EHR (clinicians' notes contained decision labels). When compared with the notes presented in patients' medical records, the rules provided consistent and detailed explanations regarding wound locations and wound tissues. We also found that VU rules required to have thin and thick slough descriptors for more accurate assessment. The revisions were made, and comprehensives of the rules were finally assured.

Fig. 1. Example of chronic wound image labeled using rules from decision table

5 Design phase two- ML system artifact

5.1 Cycle 1- Designing ML system artifact

Requirements. In the second phase as summarized in Table 1, we began the actual process of the ML artifact design using the following requirements:

Databank: A total of 2056 unlabeled wound images. There are 1695 images from a local wound clinic, 249 from publicly available web sources and 114 from previous study. Decision labels (predictions): D1 with 51 labels from expert and 25 labels from novice, D2 with 57 expert labels and 245 novice labels and D3 with 97 expert labels and 135 novice labels. *Labeling procedure*: The experts labeled the image data using their own expertise during a 3-hour session which was video recorded. The novice researcher used the decision rules and labeled the 205 images with 61 features and decision labels separately (video recording was not necessary). *Included features*: We used 9 PWAT features (eight sub-scores and the total PWAT score), wound locations, and five wound types. These together resulted in 64 one-hot encoded features. Evaluation metrics: F-1 scores (weighted as suggested for the imbalance classification problems) and area under the receiver operating characteristics (AUC). We also applied SMOTE oversampling with 3 iterations of 10-fold cross validation. *Sample*: A total of 205 images were randomly selected and labeled with D1, D2, or D3.

Table 1. Phase two of DSR: Designing ML system artifact

Relevance	A ML artifact can support non-expert clinicians with chronic wound management decisions at the point of care
Define objective	Instantiate ML artifact and demonstrate its use for non-experts
Design & develop	Trained ML artifact on 205 image samples with labels that have acceptable agreement level between expert and novice
Artifact	ML system capable of predicting wound decisions where all features are present
Evaluate & observe	Inaccurate decision labels from expert-novice inconsistency ML should be built based on the features expected to be available at the time of prediction and common to non-experts
Create knowledge	Not all expected features are available at the time of prediction
Current knowledge	Wound cleaning (debridement) is recommended for all wounds and must be included in assessment

ML Design. We experimented with most common ML algorithms that were used by several studies with promising results. These are decisions trees (DT), random forest (RF), support vector machine classifier (SVM) and XGB.

Evaluate and observe. The results from testing different ML algorithms showed above average performance for the main ML model (XGB) with overall F-1 = .806 when trained using novice data (given features and labels). When trained on expert data, the performance dropped to F-1 = .543. Table 2 depicts performance results for this initial set up of the ML artifact (XGB), recommended for fast deployment [35]).

Table 2. ML artifact prediction results - Multiclass (Cycle 1)

Classifier	Expert		Novice	
	F-1	**AUC**	**F-1**	**AUC**
DT	.530	.777	.747	.817
RF	.556	.760	.756	.800
SVM	**.587**	.814	.782	**.876**
XGB	.543	**.844**	**.806**	.862

To solve for the inconsistency, we calculated the agreement level between novice and expert (agreed on 144 images and disagreed on 61 images) and realized that lack of clear labeling procedure resulted in inconsistent decision-making between them and this may have caused 30% of the disagreement cases. We also analyzed the videos from the labeling sessions and realized there were two issues with our prior labeling procedure: First, there were times that the expert was inconsistent about giving two decision labels (D1 and D2) while referring to non-urgent and urgent cases. Second, the expert seemed troubled labeling some images due to lack of information about the current treatment the wound images were under. For example, for a wound located on the plantar foot, the expert was recommending both D1 (“I assume it is already in a cast to offload pressure”) and D2 (“this wound needs to be offloaded”). This is a common issue with most medical image datasets especially for chronic wound management where no pre-existing image database is available for routine image collection from the provider.

5.2 Cycle 2- Refining ML Artifact design

Requirements. In the second phase (Table 3), we reassessed and revised our protocol and added new assumptions that solve for current treatment ambiguities. We also resampled more images from our image databank and conducted and video recorded a new labeling session with the same expert. In that session, we used our new protocol and asked the expert to proceed with labeling based on the followings: (a) This is the first visit by the non-expert, (b) Non-expert clinician’s expertise does not include sharp debridement (c) The current wound (image) was debrided/required no debridement when the patient was sent home from the wound clinic, (d) Patient’s transportation to the wound clinic is costly, and (e) The patient has a current treatment plan based on the standard of care (control infection, perform daily dressing changes, offload, and VAC).

Table 3. Phase two of DSR: Refining the ML artifact

Relevance	A strong ML system capable of predicting wound decisions with average high accuracy from both expert and novice labels
Define objective	Solve for inconsistent decision labels by expert and novice
Design & develop	Instantiate the generalizable ML artifact with less predictors
Artifact	XGB Classifier
Evaluate & observe	Reevaluate using performance metrics to demonstrate overall capability of the ML artifact
Create knowledge	A highly accurate ML artifact can be developed based on most common factors of the wound healing as predictors
Use of the Current knowledge	This ML artifact can be integrated into a smartphone App with the ability to solve for current treatment ambiguity

We also updated the wound knowledge base with new wound features from a recent guideline [29]. These features were recommended for wounds that can benefit from regular debridement and were based on appearance of wound bed, wound edge and surrounding skin. Using these new features and new knowledge gained from the cycle 1, we designed a decision pathway (see Fig. 2) to be used for next round of labeling.

Sampled dataset: A total of random 375 images (338 training and 37 testing samples) were selected based on new criteria that matched current protocol and PWAT criteria. The images were labeled using new protocol and decision pathway shown in Fig. 2. Labeling procedure: The expert and novice used the new decision protocol and pathway to label 375 images. The expert was informed of our novel approach that solve for D1 and D2 ambiguities for POC due to lack of information about the current treatment (i.e. D1 and D2 as single decision under non-urgent class and D3 under urgent class).

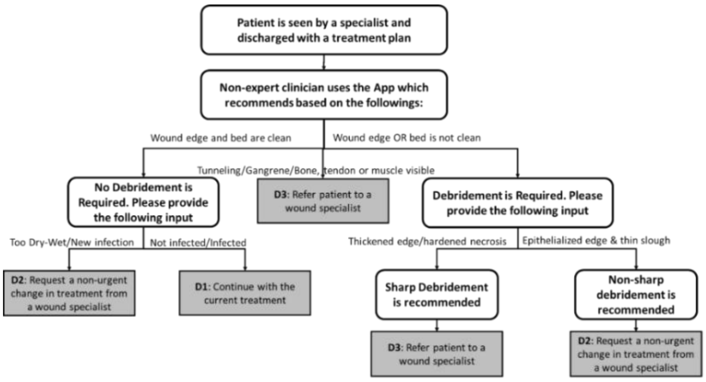
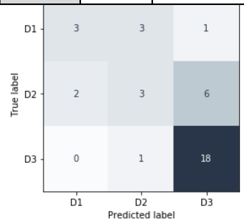
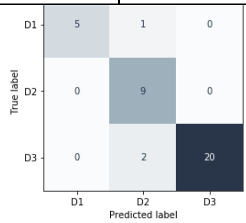


Fig. 2. The designed decision pathway used for wound assessment

The expert had this knowledge while labeling the images. There were 189 non-urgent and 186 urgent labels given by the expert and 152 non-urgent and 223 urgent labels given by the novice. The agreement between the novice and expert (Table. 5) increased to nearly 85 % (with 83% for 74 overlapping images with prior set). *Included features*: We used total PWAT, wound locations, gangrene, slough, hardened necrosis, thickened rolled edge, epithelialization, undermining and tunneling as predictors.

Table 5. ML artifact prediction results- Multiclass (Cycle 2)

Agreement when requesting for current treatment input			Expert		Novice		Both Avg.	
			F-1	**AUC**	**F-1**	**AUC**	**F-1**	**AUC**
		DC	.311	.500	.340	.500	.325	.500
		DT	.633	**.875**	**.926**	.976	.779	**.925**
Agreed	318	RF	.587	.799	.906	.929	.746	.864
Disagreed	57	SVC	.632	.812	.858	.975	.745	.893
Agreement	84.8%	XGB	**.641**	.791	.923	**.976**	**.782**	.883
The difference between expert and novice models for D1 and D2 before requesting for current treatment input is depicted						**XGB Confusion Matrix**		

ML design and evaluation. We also analyzed how the algorithms perform comparing to a dummy classifier (DC) which relies on random predictions.

In the actual labeling session (which took about 2.5 hours), wound expert had no trouble following new structured protocol and decision pathway and labeled all 375 images. We then asked the expert to label six new randomly sampled images from our ongoing image data collection from a local wound clinic (not previously known to/seen by the expert or novice) to evaluate the consistency of our new protocol and the decision pathway. After labeling these 6 new images, we revealed to our expert the clinicians' notes and actual decisions associated with those wounds seen in the clinic. The expert was in total agreement with the clinician's decisions. These 6 images were chosen to see whether "the decision pathway" is accurate and captures enough information required to make an informed decision.

When asked, the expert noted that the percent reduction in wound surface area has been demonstrated to be a strong predictor of healing for venous and diabetic foot wounds [36, 37]. Consideration of percent area surface reduction in comparing wound image sequences would be of value in determining the decision pathway, using the existing assumptions. The ambiguities for current treatment were also solved using our current decision pathway using one simple rule that ask whether any current treatment was already given. This simple input at the point of care can raise the confidence of the ML system's predictions.

6 Conclusion

This study demonstrated, through DSR, the development of a ML artifact that can predict wound care decisions generalizable to contexts where both novice and expert clinicians may be facing. Results of the artifact evaluation demonstrated the acceptable prediction performance of the ML artifact that uses XGB model with average F-1 = .782 for both novice and expert decision makers. All the algorithms performed better than the dummy classifier that uses random predictions. These results also demonstrate that this prediction capability for XGB ML artifact can be achieved using image data (common wound features as predictors and decisions as labels) that are given by either novice or expert. The most predictive features are *thick slough or hardened necrosis*, *thickened rolled edge*, *total PWAT*, *thin slough*, *anterior leg and dorsal toe*, respectively which confirm the usability of our designed decision pathway.

Comparing to the current wound care solutions that require experts to make treatment decisions [25-27], our ML solution provides POC decision support using wound features that non-expert clinicians commonly report when documenting wounds. Non-expert clinicians provide most of the wound care within the wound care community and their ability to determine wound conditions at the appropriate time directly affect the quality of treatment these patients receive. Although current solutions provide tools to efficiently document these common wound features, non-experts' inabilities to determine the correct decision pathway (when certain features are present) at different stages of chronic wound development results in delayed and thus more aggressive treatments (often surgical amputations) that cost a lot for the patients and their families.

7 Limitation and future research

This study has some limitations. First, our sample size of 375 wound images with no clinical notes (decisions and measurements) may not be enough to demonstrate generalizability of the ML artifact due to the wound care domain that has limited available image datasets with associated clinical notes. In this challenging environment, we showed several demonstrations prior and post development of a high performing ML artifact through iterative design cycles. Future research can address this by adding into the ML artifact database the wound surface area measurements and comparison with subsequent images to calculate the percent change. Moreover, user adoption and effective delivery of the predictions from our ML artifact to the final user provide rich opportunities for future research. Second, in current study a non-expert clinician was considered a novice researcher. Although this may be another threat to generalizability (when ML artifact is used by real-world users), we expect their agreement level with experts to be higher thereby allowing for higher ML performance. The next phase focuses on the design and evaluation of a smartphone App using image processing techniques that allow for automatic feature extraction of our predictors.

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