

Woubot®: A personalized predictive AI system for hard to heal wounds*

Elaine Taylor Whilde^{1,*†}, Janine Lane^{1,2}, Chris Dickson³, Syeda Mah-e-Fatima⁴, Qurratal Ain Fatimah⁵ and Ali Hasnain^{6,*†}

¹Nine Health Global Ltd, Leeds, UK

²University Hospital Galway, Ireland

³School of Pharmacy and Biomedical Sciences, Royal College of Surgeons in Ireland, Dublin

Abstract

Management of chronic wounds in healthcare disciplines is a huge financial burden on healthcare systems around the world. An estimated 1.5 – 2 million patients in Europe alone suffer from acute or chronic wounds at a given time. The mental and societal burden of living with a chronic wound is immense. Many studies have shown that treatment of these wounds conservatively (without surgery) is one of the major contributing factors to the cost, with wound dressings being a significant impact. Data from the NHS shows that managing wounds properly such as choosing the appropriate dressing for the right wound and continuous appropriate treatment can significantly increase healing and reduce healthcare spending. Funded by the National Institute of Health Research and NHS England the AI in Health and Care Award Accelerated Access Collaborative (AAC) and NHS AI Lab supported AI technologies across the spectrum of development, from initial feasibility to evaluation within clinical pathways in the NHS and social care settings, to the point that they could be nationally commissioned. In this paper, the findings of a phase 1, project a feasibility study are introduced for discussion and shared learning about an artificial intelligence-based technology which aims in phase 2 to predict the development of hard to heal wounds and their rates of healing and produce recommendations for clinicians dealing with wound care. Woubot® will evaluate the risks of different wound treatments and predict and monitor the progression of wounds. Considering national guidelines on treatment as well as data available, improvements in practice will be recommended, and tailored treatment plans will be suggested for individual patients.

Early analysis of patient data (combined electronic clinical records containing demographic, historical, laboratory tests, intervention details etc.) was completed over a 12-month period. The impact of biological factors affecting wound healing suggested that changes in clinical practice such as carrying out a blood test to detect for example vitamin B12 levels and other circulatory factors could significantly improve wound healing rates. The findings suggest that once detected either simple lifestyle changes (diet) or a clinical intervention e.g., B12 injections may result in improved healing. Initial assessments show the monetized benefits of using Woubot® have been predicted to be around £35 million over a period of 10 years, which is a substantial development in the future of wound management.

Keywords

Chronic Wound, Artificial Intelligence, Woubot®

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*Corresponding author.

†These authors contributed equally.

✉ elaine.taylor-whilde@ninehealth.global (E. T. Whilde); alihasnain@rcsi.com (A. Hasnain)

🌐 <https://www.rcsi.com/people/profile/alihasnain> (A. Hasnain)

🆔 0000-0002-1755-4398 (E. T. Whilde); 0000-0003-4014-4394 (A. Hasnain)



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1. Introduction

Approximately 2.2 million patients currently have a chronic wound [1]. The annual NHS cost of managing these wounds and associated comorbidities in 2017-18 was £8.3 billion. With 81% of this spend in the community [1]. The annual prevalence of wounds rose by 71% between 2012-2013 and 2017-2018 with an increase in resource utilization of 48 % during this period [1]. There is little information available at the time of writing post-Covid pandemic; however, it would be a reasonable assumption that these figures are worsening. Up to 40% of chronic leg wounds never heal, leading to serious complications and even death.

Artificial Intelligence software name Woubot® is being developed to predict and produce a series of personalized care recommendations for frontline clinicians based on national evidence. There is considerable variation in practice and outcomes [2] which increases care costs and extends healing times [3] Starting with a prototype Application Programming Interface (API – it will be able to link new software with current healthcare systems) developed in partnership with the NHS and funded by the Artificial Intelligence in Health and Care Award,¹. we have created a secure data processing environment managed by Nine Health Community Interest Company NHCIC (part of the NHS family) and hosted by an accredited public sector data host. Clinical algorithms have been developed based on national clinical evidence supporting the work of the National Wound Clinical Strategy Programme (NWCSP)² which will be tested in this secure environment with the aim of monitoring and measuring adherence to these national standards for wound care. The software will create a personalized care pathway with a series of recommendations for use in the NHS via a mobile app. Most of this care will be delivered by nurses and other healthcare professionals in clinics and the community. Recommendations, whether for exercise, other lifestyle changes medication or dressings, will be individualized for each patient based on their history and biological makeup (using predictive indicators) and linked to the latest clinical evidence. Building on our understanding of what predicts those at risk of developing hard-to-heal wounds we are designing a randomized controlled trial to compare the use of the software tool against standard care for people with hard-to-heal wounds. AI involved in this type of clinical support is classed as a medical device and needs formal regulation via the UK's Medical HealthCare products regulation Agency (MHRA). A clinical trial in order to gather this evidence of effectiveness for this is essential. A lead for patient and public involvement will ensure the study plan and ongoing support involves those accessing services. The work will involve working together with NHS hospitals, networks, and facilities in London and Yorkshire. The software will be available, after subsequent development, to the wider NHS through its national innovative technology pathways, publication, and National Institute for Health and Care Excellence (NICE) . Artificial Intelligence software name Woubot® is being developed to predict and produce a series of personalized care recommendations for frontline clinicians based on national evidence. There is considerable variation in practice and outcomes [2] which increases care costs and extends healing times [3] Starting with a prototype Application Programming Interface (API – it will be able to link new software

¹Woubot® - an A.I. predictive system to produce personalized care recommendations for chronic lower limb wounds https://fundingawards.nihr.ac.uk/award/AI_AWARD01723(lastaccessed:14/03/2022)

²National Wound Clinical Strategy programme. <https://www.nationalwoundcarestrategy.net/about-the-nwcsp/> (lastaccessed:14/03/2022)

with current healthcare systems) developed in partnership with the NHS and funded by the Artificial Intelligence in Health and Care Award we have created a secure data processing environment managed by Nine Health Community Interest Company NHCIC (part of the NHS family) and hosted by an accredited public sector data host. Clinical algorithms have been developed based on national clinical evidence supporting the work of the National Wound Clinical Strategy Programme (NWCSP) which will be tested in this secure environment with the aim of monitoring and measuring adherence to these national standards for wound care. The software will create a personalized care pathway with a series of recommendations for use in the NHS via a mobile app. Most of this care will be delivered by nurses and other healthcare professionals in clinics and the community. Recommendations, whether for exercise, other lifestyle changes medication or dressings, will be individualized for each patient based on their history and biological makeup (using predictive indicators) and linked to the latest clinical evidence. Building on our understanding of what predicts those at risk of developing hard-to-heal wounds we are designing a randomized controlled trial to compare the use of the software tool against standard care for people with hard-to-heal wounds. AI involved in this type of clinical support is classed as a medical device and needs formal regulation via the UK's Medical HealthCare products regulation Agency (MHRA). A clinical trial in order to gather this evidence of effectiveness for this is essential. A lead for patient and public involvement will ensure the study plan and ongoing support involves those accessing services. The work will involve working together with NHS hospitals, networks, and facilities in London and Yorkshire. The software will be available, after subsequent development, to the wider NHS through its national innovative technology pathways, publication, and National Institute for Health and Care Excellence (NICE)³.

2. Background

Wounds are prone to infection. They are distressing and painful and have a negative impact on a patient's mobility and quality of life. England's community prescription costs are over £110 million annually, with additional NHS costs. The global wound care market forecast is 24.8 billion US dollars by 2024 segmented into hospitals, clinics, and home healthcare². An estimated 278,000 NHS patients had venous leg ulcers (VLUs) in the UK in 2012. By 2025, over five million patients in England will have diabetes, of which there is a 25% incidence of foot ulcers. In people with diabetes, 80% of ulcers progress to amputation, and after one amputation patients are twice as likely to have a second. With a five-year mortality rate of more than 50% in diabetes patients with foot ulcers and 80% in patients who have had a diabetes-related amputation, diabetes foot ulcer five-year mortality rates are similar to or worse than many types of common cancers [4, 5]. The inpatient cost of treating diabetic foot ulcers (DFUs) is £6.6 million⁴ [2]. The mean cost of treating a single DFU is £7600 (£3,000 per patient healed and £13,500 per patient unhealed). Globally, 3% of the total worldwide population have leg ulcers with some patients having repeat cycles of healing and un-healing wounds. Many factors

³National Institute for Health and Care Excellence (NICE). <https://www.nice.org.uk/> (last accessed:14/03/2022)

⁴Diabetic foot problems: Prevention and management. <https://www.nice.org.uk/guidance/ng19/evidence/full-guideline--august-2015-pdf-15672915543> (last accessed:14/03/2022)

influence wound healing. Knowledge of the safety, clinical, and cost-effectiveness of thousands of dressings is necessary. GPs and nurses usually manage wounds in the community and as of now, there are 43,440 community nurses and 287,000 nurses in England⁵. The Department of Health and Social Care NWCSP teams have produced an industry specification for application suppliers to the NHS. These standards will be used to integrate with local NHS solutions in Humberside and southwest London. The NWCSP has identified that the NHS needs:

- A more granular data capture for business and clinical purposes.
- Point-of-care mobile technology and apps.
- A national high-level specification (work in progress).
- Supplier engagement.

3. Related Work

Specialist intellectual property lawyers performed a freedom-to-operate search and did not identify any comparable products. There are a range of commercial wound measuring applications on the market in the UK and EU some of which notably for example. Medinnoscan⁶ which is a Hungarian government-funded product uses AI to measure the size and nature of] the wounds. Nine Health Global is engaging over the next few months with Medinnoscan and two of the main wound app suppliers to the NHS to explore potential integration into a single app which will assess the wound, predicting outcomes and personalizing the wound care.

One of the key differentiators of working with health care data is its sensitivity and the impact of a broad range of data laws on accessing, processing, and applying AI. Patients, the public and clinicians need to be able to trust the AI and the analysis should be transparent with the ability to track and audit results.

The experience of joining an EU (FP7) framework⁷ award with 22 partners across eight countries to create an info structure- the Virtual Physiological Human (VPH)⁸ laid the foundations for Nine Health to translate this learning and ability to securely access and process health data for use with practical commercially available AI products.

Four flagship workflows (from @neurIST⁹, euHeart¹⁰, VPHOP¹¹, Virolab¹²) provided existing data, tools, and models and engaged with the services developed by VPH-Share to drive the development of the infostructure and pilot its applications.

⁵The number of nurses and midwives in the UK. <https://fullfact.org/health/number-nurses-midwives-uk/>(lastaccessed: 14/03/2022)

⁶MEDINNOSCAN. Medical Diagnostic Artificial Intelligence. <https://medinnoscan.com/en/home-2/>(lastaccessed: 14/03/2022)

⁷7th Framework Programme for Research. https://ec.europa.eu/commission/presscorner/detail/de/MEMO_16_146(lastaccessed:05/03/2022)

⁸Virtual Physiological Human: Sharing for Healthcare - A Research Environment. <https://cordis.europa.eu/project/id/269978>(lastaccessed:05/03/2022)

⁹@neurIST- Integrated Biomedical Informatics for the Management of Cerebral Aneurysms. <http://www.aneurist.org/>(lastaccessed:01/03/2022)

¹⁰euHeart - Matters of the Heart. <http://www.euheart.eu/>(lastaccessed:12/03/2022)

¹¹Osteoporotic Virtual Physiological Human. <https://cordis.europa.eu/project/id/223865>(lastaccessed:05/03/2022)

¹²A Virtual Laboratory for Decision Support in Viral Disease Treatment. <https://www.virolab.org/>(lastaccessed: 05/03/2022)

Data sources were usually pseudonymized clinical data from patients - sometimes with population information. The project involved secure access and storage with annotation, inference, complex image processing, and mathematical modelling. Following the successful completion of VPH-share the NHCIC team then took the learning and knowledge into China partnering with a Chinese SME Lantone in 2014 to create an artificially intelligent basic diagnosis system for grass route doctors known as Diagbot¹³. Diagbot has enabled the development of Woubot by developing the technology necessary to apply the principles of an artificially intelligent diagnosis system to the complex treatment of a specific clinical area.

3.1. Diagbot

Diagbot uses Chinese national clinical guidelines to create a robust evidence base from which clinical algorithms (these flow charts or decision trees have been used manually and in basic computer systems for the many years in the NHS and are developed by specialized clinical reviewers and others nationally in many countries worldwide) can be run automatically on the patient's Electronic Medical Records (EMRs). The system uses Natural Language Processing (whilst most health data is referred to as structured data in the UK, in China it was largely unstructured text where understanding context etc. had to be extracted from digital copies of handwritten notes) to identify clinical terms, these are then analyzed by searching for key fields from the patient's history such as symptoms, examination results, etc., which are trained via neural networks (using patented mathematical models) producing a suggested diagnosis and treatment recommendations based on the clinical evidence (as shown in Figure 1).

4. Methodology

Using knowledge and algorithms from the Woubot® prototype system the risks of different wound healing approaches will be evaluated; predicting modifiable clinical outcomes such as time to healing, time to amputation, and death; and identifying optimal treatment plans for individual patients. Combining national assessment criteria with routinely reported data (Hospital Episodes Statistics/Community Service Data Sets) plus local data collection, improvements to prognosis and treatment will be created. Using unique algorithms to forecast patient risks and outcomes based on profiling and other personalized physiology, resources will be targeted effectively, especially where existing demand outstrips clinical capacity. The product will increase diagnosis and treatment efficacy, saving wastage on ineffective dressings and nursing and clinical time, and reducing amputations and deaths. The automated workflow will increase the speed of analysis and productivity, saving time and cost. Using patient pseudonymized data sources, algorithms will accurately find and tailor data, automatically saving thousands of hours of clinical and management time. A list of nationally validated wound assessment domains and sub-domains (potential assessment criteria) is now launched in the NHS but mainly collected manually. Woubot® will be informed by the following areas where existing data is collected:

- Clinical needs.

¹³Nine Health Global Clinical Systems. <https://ninehealth.global/clinical-systems/>(lastaccessed:12/03/2022)

Technology Support-Artificial Intelligence

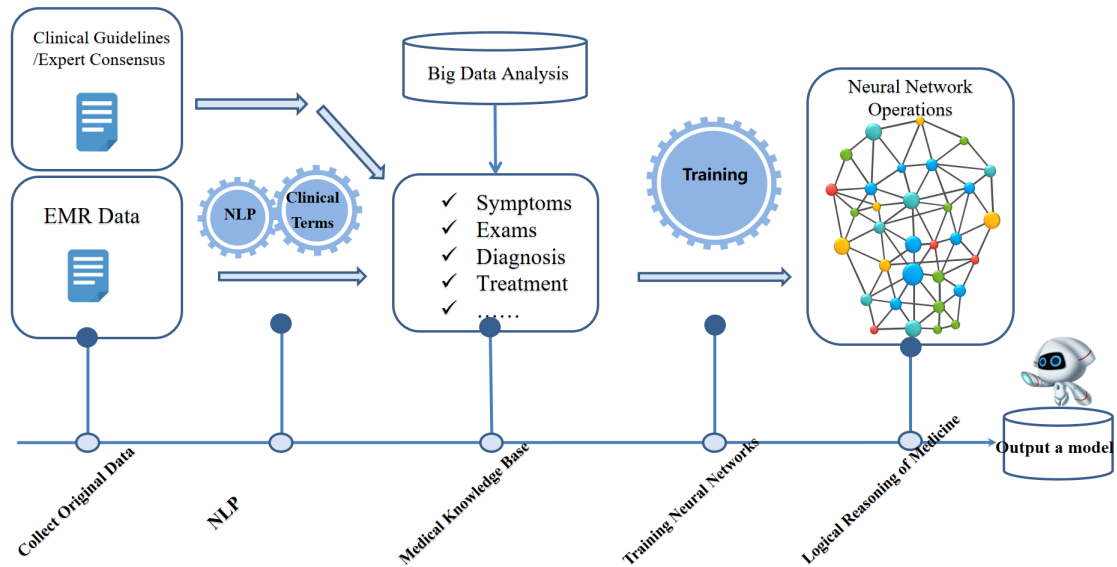


Figure 1: Diagbot Architecture

- Pathologies showing an etiology that requires a multidisciplinary approach.
- Information flow for complex pathologies.
- Diagnostic tools and data.
- Related data, based on clinician's experience.
- Experience to process a therapeutic decision
- Interpretation, bias, human error leading to misdiagnosis.

The scale of data generated, processed, and exchanged would normally require massive computing power and data storage, and sophisticated software tools. The secure NHCIC data environment will enable:

- Model homogenization; and
- Algorithm distribution for various levels of modelling.

Woubot® technology will automatically help predict those at risk of developing chronic wounds and will be able to produce a series of recommendations for the clinician (healthcare professional), usually a community nurse. It will evaluate the risks associated with different wound healing approaches, predict clinical outcomes, and identify an optimal treatment plan for each patient based on numerous factors. It will match a combination of products for that patient from more than 70 cellular and tissue-based products available on the market, and more than 3,000 other advanced wound-dressing products. In phase 1, led by an advisory group to ensure patient and public involvement from the spinal injury's association and the National Wound Clinical Strategy programme, a secure platform hosted by UK Cloud (NHCIC is a research data

Table 1
Patient Records (selected)

Antecedents	Person Social changes
Contact (interactions)	Allergies
Person measure changes	Person test changes
Diagnosis	Vaccines
Person Biologic Changes	Treatment
Prescriptions	Products

organization with an NHS organizational code) for data sourced from Cegedim THIN¹⁴ and the NHS Community Data set (NHS Humber Teaching Trust) using patient pseudonymized data sources (which have gone through the double de-identification process). Data was reviewed by a statistical expert to exclude bias and included a national sample from primary care and a local sample from Hull and East Riding where the demographic includes both inner-city, city, and rural and a diverse range of nationalities including Black, ethnic, and minority groups aged 19-80. It is also worth noting that data used was following FAIR data principles for all implementation considerations [6, 7].

5. Research Data Flow

Using a single application via the Integrated Research Application System (IRAS)¹⁵ and Health Research Authority (HRA)¹⁶ permissions were obtained at the start of the 12-month phase 1 project and were accelerated by applying before the project start date. An application was submitted to Cegedim THIN, a world-leading high-quality longitudinal, anonymized, and representative real-world primary care patient data source. Following successful approvals research data applications are processed by THIN within approximately 3 weeks. 1700 anonymized full patient records from those with Diabetic Foot Ulcers and Venous leg ulcers over a continuous 2-year period aged 19-80 were obtained using READ codes¹⁷ and included the following records.

5.1. Patients Records

Exclusions were:

- Children and young people under 18
- People over the age of 80
- Patients with cancer or on chemotherapy
- Immuno-suppressed patients

¹⁴Cegedim THIN: The Health Improvement Network. <https://www.cegedim-health-data.com/cegedim-health-data/thin-the-health-improvement-network>.(lastaccessed:12/03/2022)

¹⁵Integrated Research Application Systems. <https://www.myresearchproject.org.uk/>.(lastaccessed:05/03/2022)

¹⁶NHS, Health Research Authority. <https://www.hra.nhs.uk/>.(lastaccessed:14/03/2022)

¹⁷READCodes.<https://digital.nhs.uk/services/terminology-and-classifications/read-codes>(lastaccessed:05/03/2022)

- People with a record of self-harm
- Patients with Rheumatoid Disease

Bias was eliminated in the following ways:

- trimming the data (remove outliers / small number results)
- removing data with the absence of missing key variables (omitted variable bias)
- time interval bias – data taken over two years to reduce bias in results
- key sample size calculation from the data taken to ensure equal numbers of Sex
- 95% confidence intervals to make sure sample groups taken from the data e.g., race are representative of the population.
- tests for degrees of association between variables – leg wound and wound healing
- computation of descriptive statistics, reporting on inferential statistics, consider effect sizes, correlations, and differences
- calculation of sample size (data from previous studies unavailable to determine effect size) so effect size
- calculated on the minimum effect size considered important (sample size to attain 80% power) for correlation analysis

Other points to note were that:

- Relationship analysis between variables - analysis that forms a valid and reliable measure of wound healing
- Relationships can be formed between the dependent variable (the leg wound) and individual data items as predictors of wound healing.

Data on a further 200 anonymized patients from the NHS Community was also obtained but was not combined with the above data as the THIN dataset had been subjected to robust bias checks to ensure that it was balanced (Figure 2). The sampling strategy was random (all wounds) and good representation of the population – (cases selected at random) Sample size calculation was all wounds defined consistently and as a valid and reliable measure of wound healing.

Semantic web technologies were not used in the feasibility study as we did not link data from different collections and in the 12-month timescale this was not possible. In the next phase, we will explore the possibility of using linked data within the NHS rules where an organization such as NHS Digital carries out the linkage by supplying pseudonymized linked data. In this case, the data is linked across national data sets using a pseudonymized key known only to NHS digital. Sensitive fields which could be used to identify individuals are also removed.

The figure³ shows how data is accessed from national, local, and specific health data collections (of which there are several thousand routinely collected in the UK). Data is structured and coded clinically, for GP data this was READ Coded 18(as used in the feasibility study) but most data from GP, hospital and community systems are now using a globally accepted nomenclature, SNOMED Clinical Terms¹⁸. SNOMED International is a not-for-profit organization that owns,

¹⁸SNOMED Clinical Terms. <https://www.snomed.org/>. (last accessed:22/04/2022)

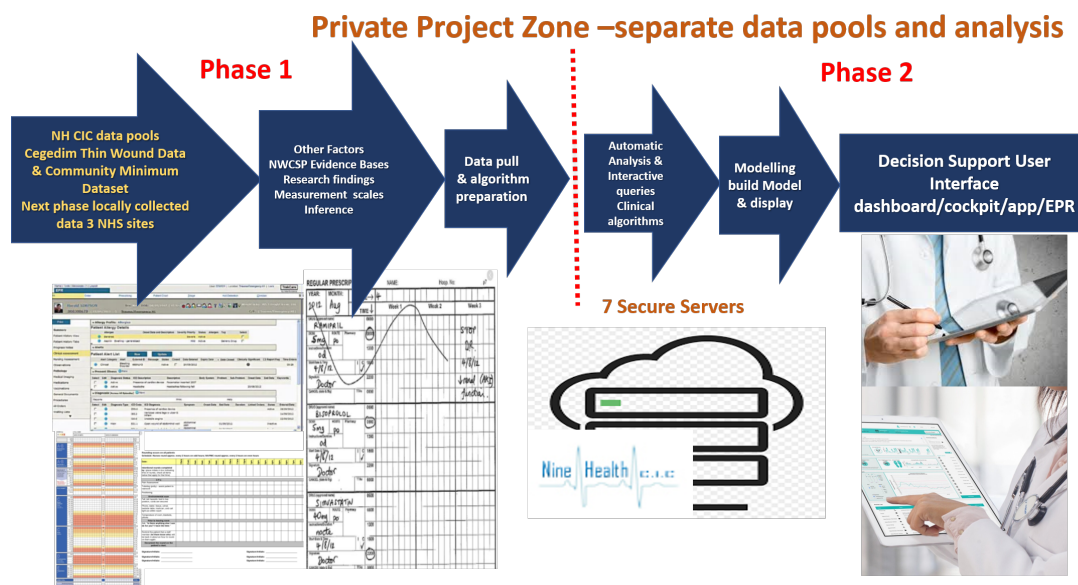


Figure 2: Application Data Flow

administers, and develops SNOMED Clinical Terms, the world’s most comprehensive clinical terminology. This is far richer and is standardized across countries that use the SNOMED licenses. Once accessed then the data is securely stored and is only accessed by NHS approved and trained analysts based in the UK. The analysts prepare data queries using SQL and using python construct visualizations, carry out statistical analysis, and can identify patterns in the data supporting the predictive components of the analysis. This process was completed in the feasibility study for a narrow set of parameters around diabetic foot ulcers. (Modules 1-3 in the figure 3) .In the next phase (Modules 4-6), many more parameters around wound healing and venous ulcers will be used to validate the early results. The algorithms prepared in phase 1 will be run on more national data sets as well as locally collected data through the clinical trial. Working with the NHS pilot sites, patient representatives, and application developers we will build new models and create an application with user-designed interfaces before integrating with existing NHS systems.

6. Early Results

Detecting a raft of modifiable predictive factors such as Vitamin B12 levels and the impact of BMI on healing, time to amputation was analyzed isolating the key measures enabling the prediction of time from developing diabetes to developing a foot ulcer. The ability to predict an amputation could be deduced by the automated analysis of the following factors: a) Hb_A1C_Diabetic_Control, b) Blood Glucose, c) HDL/LDL Ratio, d) Triglycerides, e) BMI.

The dressings used and their size over time were analyzed finding the most used dressing and the least used and the impact that they had on healing over time using size as a proxy for

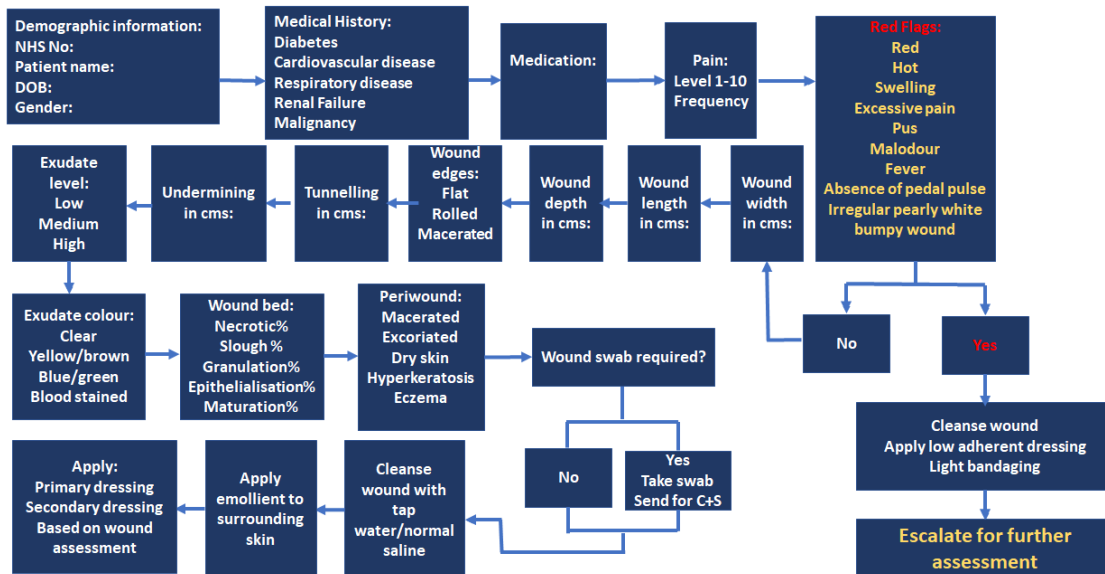


Figure 3: Assessment for a wound above the malleolus and above knee

healing.

Clinical algorithms were developed based on the national wound guidelines produced by the NWCSP for some parts of the patient pathway e.g., initial assessment including red flags (as shown in Figure 3). Based on new national recommendations and updated regularly using local formularies (clinical teams prepare these guidelines for local use) these will be tested in a secure environment with the aim of monitoring and measuring adherence to these national standards for wound care. Using artificial intelligence to identify people likely to develop chronic leg wounds and to manage their preventative care will (in those that already have leg wounds, such as diabetic foot ulcers (DFUs)), ensure that evidence of effective treatment is turned into simple steps that are available quickly to front-line staff.

The example below is a step-by-step guide for a basic clinical assessment by a front-line practitioner (usually a community nurse) and will appear in the app as a series of questions with yes/ no answers. Currently, At the moment such assessments are carried out on paper questionnaires and then entered into computer systems manually by the nurse at the end of every day.

This is cumbersome, time-consuming, and creates much scope for error and lack of continuity as several different nurses are often involved in each patient’s care. The app will automatically indicate “red flags” which are critical indicators needing urgent attention and immediate onward referral to expert clinics. In the UK there is a shortage of experienced, qualified tissue viability nurses with these assessments being carried out by relatively inexperienced staff meaning that currently, these red flags may not be immediately detected contributing to poor wound healing.

A cost-benefit analysis was carried out by an independent evaluator who identified a societal gain of £35 million mainly from avoided death and amputations. Monetized benefits of Woubot® over a 10-year period for a cohort of 100 patients would be:

- Cash Releasing £4,075
- Non-Cash £2,317,603
- Societal £35,541,748
- A total of £37,863,426

7. Recommendations

Further automation of processes, combining existing data collected by the National Minimum Wound Assessment Data Set, THIN data sets, and NHS digital HES, CSDS, and other local data is needed to develop a complete commercial product.

The research aims of phase 2 are to obtain clinical validation and measure patient outcomes using Woubot®. The methodological considerations below enable Woubot® to overcome bias in settings (experimental vs. real world), population (representative, size, and follow-up data), and data (collection methodology and quality).

1. What factors predict those at risk of developing hard-to-heal wounds? (building on the prototype results above) creating evidence of the factors that predict hard to heal wounds
2. Can Woubot® generate personalised recommendations (based on National Guidelines) and predict outcomes for patients with hard-to-heal wounds? The aim is to measure the performance of Woubot®. Predicted probabilities will be compared to real probabilities in novel datasets to overcome multiple biases.
3. Are Woubot®-generated personalised recommendations more effective than standard care for patients with hard-to-heal wounds? A randomised controlled trial aims to establish whether the implementation of Woubot® in clinical practice reduces the healing duration of reference ulcers in patients with hard-to-heal wounds. Secondary outcomes will be evaluated, including a range of patient-related outcomes and cost benefits.

8. Conclusion

Wounds, especially chronic wounds place a significant burden on both the patient, as well as the health care system. Chronic wounds have been identified to be different from acute wounds, with different management required for the optimal outcome. Artificial Intelligence based Woubot® technology is being developed with the purpose of analyzing different stages of wounds, and using existing, available patient data, to predict the best treatment options that a clinician can use to better manage long term wounds that may result from venous leg ulcers and diabetic foot ulcers, to name a few causes of chronic wounds. Patients and clinicians both will benefit immensely from software that can accurately predict treatment pathways that will reduce the time and cost of healing involved for a long-term wound. Cost-benefit analysis has shown a societal gain of £35 million over a course of 10 years. Phase 2 of the project will involve obtaining clinical validation and measuring patient outcomes using Woubot® technology.

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