Technoleg Iechyd Cymru
Health Technology Wales

Evidence Appraisal Report[1]

Integrated Digital Wound Care Management Systems to assess and manage people receiving wound care

Appraisal summary

Why did Health Technology Wales (HTW) appraise this topic?

In Wales, around 80,000 people present to their general practitioner with a new wound each year. It has been estimated that, across the UK, wound care accounts for £8.3 billion of NHS costs annually. Wound care is complex and involves full assessment of the patient, diagnosis, measurement, assessment, and documentation of the wound, development of a treatment plan and often includes repeated follow-up visits. Wound care is provided by many different health care professionals (HCPs) including doctors, nurses, podiatrists, wound care specialists and health care assistants and may involve self-management from the person and their carers. The National Wound Care Strategy Programme considers that high quality documentation, which includes accurate wound assessment, use of digital images of wounds, and efficient sharing of information between HCPs, to be an essential component of effective wound care. However, it has been observed that documentation is frequently inadequate and that changes to treatment are made without explanation. Wounds are typically measured using paper rulers, which may have poor accuracy and poor reliability between visits, measurement may not occur at each follow up and digital images are not routinely available.

Integrated Digital Wound Management Systems (DWMS) incorporate use of a digital device, to image the wound in three dimensions and automatically measure wound boundaries and wound bed tissue type using software or artificial intelligence algorithms. The automatic process is claimed to improve accuracy and reliability of measurements. The device is also used to document all other aspects of wound assessment and treatment plans at point-of-care. Documentation is uploaded to a centralised, secure, digital dashboard or portal where the patient's wound care can be managed remotely and reviewed by specialists in wound care. The dashboard allows the entire wound caseload to be reviewed, and patients prioritised depending on clinical need. The dashboard can send assessments and care plans to individual patient's electronic health records (EHRs). Due to the available evidence, HTW researchers conducted a broad evaluation of DWMS systems available globally. Minuteful for Wounds (Healthy.io) and eKare Insight (eKare) are two CE marked DWMS systems that are being piloted by NHS organisations in the UK. Two other systems, Cares4Wounds (Tetsuyu Healthcare) and Wound Viewer (Omnidermal) are CE marked, and two, Swift Skin and Wounds (Swift Medical) and Tissue Analytics (Net Health) have approval in the US or Australia.

The topic was submitted by a commercial manufacturer.

[1] Cyfieithu dogfennau HTW wedi'u cyhoeddi o'r Saesneg i'r Gymraeg
Translation of published technical HTW documents from English into Welsh

What evidence did HTW find?

The aim of this report was to identify and summarise the evidence that addresses the following question: What is the clinical and cost effectiveness of integrated digital wound care management systems compared with standard care?

We identified and included two distinct types of evaluation for DWMS. One type of evaluation consisted of nine cross-sectional studies examining reliability and/or concurrent validity (agreement with conventional measures taken at the same time) of the automatic assessment component of DWMS systems. The other consisted of studies describing use in practice of some, or all, of the components of DWMS. We identified eight such studies. One was a non-randomised comparative study, three were prospective cohort studies with historic comparators, two were single arm prospective cohort studies and one was a service evaluation. The final study was a time and motion study evaluating time taken to complete and upload an assessment using DWMS. We were also provided with an unpublished report describing real-world evidence collected by Healthy.io. The published service evaluation was linked to this report.

Not all systems with validated imaging systems have published studies with effectiveness data (Insight and Wound Viewer) and not all systems publishing effectiveness have published validation studies (Minuteful for Wound).

Overall, there was consistent evidence that the automatic measurement component of DWMS can produce reproducible surface area measurements. Reproducibility was good when the same HCP took an image of the same wound several times, and when different HCPs took an image of the same wound. When compared with traditional measurements, such as paper rulers or wound tracing, there was good evidence that the surface area measurements by DWMS showed agreement. One study examined depth and volume and found poor reproducibility for depth, but good reproducibility for volume. Two studies examined concurrent validity for depth and volume and found no agreement between DWMS and the reference measures, which were cotton swabs for depth and the volume of saline solution filling a wound.

There are uncertainties about reliability and validity of wound measurements conducted outside of controlled settings. The studies evaluating reliability and/or concurrent validity were all conducted in healthcare settings, with imaging performed by HCPs. Most studies reported mean or median wound sizes of between 3 cm^2 and 10 cm^2. There were qualitative reports that small wounds, very large wounds, wounds in skin folds or in contouring areas of the body were challenging for the systems to measure, and wound boundaries needed manual adjustment. In addition, three studies conducted in Singapore with mainly Chinese, Malay, or Indian patients commented that wounds on darker skin tones were also more likely to need manual adjustment. We did not identify any validation studies where patients or carers took images in their own homes.

The eight studies that reported on aspects of clinical effectiveness were pilot or feasibility studies that aimed to test whether implementation of DWMS was practical. There was a wide variation in study procedures and the settings and types of wounds varied. Studies were conducted in hospital wards, nursing homes, outpatients' clinics, and patients' own homes, and included patients as well as HCPs taking and uploading wound images. Images were uploaded to a dashboard for review by wound care specialists and, in some studies, patients could contact specialists directly via the DWMS. Follow-up times varied from eight weeks to twelve months. It appears that implementation of DWMS is feasible in a wide range of settings. The research evidence is supported by a large amount of real-world data from three sites in the UK where roll-out appears successful.

There is evidence that patient satisfaction with using DWMS was good, although in one study where patients uploaded their own images, over a quarter of patients were non-adherent. In addition, in another study where patients uploaded images, high numbers of eligible patients were excluded due to inability to use a smartphone or lack of access to a suitable smartphone. There is some evidence that wound documentation may improve, and consistent evidence that assessment time is faster when HCPs measure wounds using DWMS. Although wound healing outcomes were reported, demonstrating that it was feasible to collect the data, we were unable to determine whether wound healing improved after introduction of DWMS. We were not able to obtain real world evidence comparing wound healing outcomes between DWMS and usual care. There was evidence that the percentage of patients experiencing complete closure of a wound within 12 weeks improved from the first three months after adoption compared to the final six-to-eight-month period for vascular wounds, however there was no difference reported for diabetes related wounds.

In addition to uncertainties around wound healing outcomes, DWMS is a complex intervention that can be implemented differently in different settings. This means that studies conducted in one setting may not be generalisable elsewhere. No relevant health economic evidence was identified for DWMS interventions. HTW conducted a simple cost analysis based on the cost of the device, which was calculated using data from the manufacturer, and resource use based on a study included in the effectiveness section of the Evidence Appraisal Report. This was used to determine the number of assessments per week which would be required for no additional costs to be realised. Manufacturer data on current use of Minuteful for Wounds suggests that it is unlikely that use of the device would translate to cost savings.

Key organisational issues to consider include reliable and secure transfer of data, and the capacity to integrate with existing data management systems across multiple settings; whether DWMS should be used in acute care where wounds may be more complex, and equity of access to care for all patients.

What was the outcome of HTW's appraisal?

HTW is a national body working to improve quality of care in Wales. We collaborate with partners across health, social care, and industry to issue independent guidance that informs commissioning within Wales health and social care. We are supported by an Assessment Group, who ensure our work adheres to high standards of methodological and scientific rigour, and an Appraisal Panel, who consider evidence within the Welsh context and produce HTW guidance. More details on our appraisal process, the assessment group, and the appraisal panel can be found on the HTW website.

In this case, the HTW Assessment Group considered the evidence presented in this Evidence Appraisal Report (EAR051) and developed guidance with concluded that there was insufficient evidence to support routine adoption. Please refer to the HTW website for full guidance details.

Evidence Appraisal Report 051 follows below and provides full details for this topic. More comprehensive details of the HTW Guidance and HTW Appraisal Panel considerations can be found on the HTW website.

1. Purpose of the Evidence Appraisal Report

This report aims to identify and summarise evidence that addresses the following question: What is the clinical and cost effectiveness of integrated digital wound care management systems compared with standard care?

Evidence Appraisal Reports are based on rapid systematic literature searches, with the aim of identifying the best published evidence on the effectiveness and cost-effectiveness of health and social care technologies and models of care and support. Researchers critically evaluate this evidence. The draft Evidence Appraisal Report is reviewed by experts and by Health Technology Wales multidisciplinary advisory groups before publication.

2. Context

Wounds have a significant impact on patients, affecting physical, psychological, and social well-being. In 2017/2018 an estimated 3.8 million people across the UK had a wound that was being managed by the NHS, an increase of 71% since 2012/2013. The estimated cost of wound management was £8.3 billion. In Wales in 2016, 78,000 people presented to their GP with a new wound, there were 15,000 wound-related hospital admissions, 68,000 outpatient appointments and 700,000 district nurse visits at an estimated cost of £330 million (Welsh Wound Innovation Centre 2017).

Around a third of people with wounds are aged over 65 years and 95% have at least one other comorbidity, with over half having cardiovascular disease, musculoskeletal disorders, or diabetes (Guest et al. 2020). Wound assessment and care is complex and includes a medical and surgical history of the patient, diagnosis and documentation of the cause of wounds, wound status, consideration of factors that may delay healing, and development of a treatment plan (Ousey & Cook 2012, Professional Record Standards Body 2023). In practice wound care is provided by different health care professionals (HCPs) including doctors, nurses, podiatrists, and wound specialists, although wound management is usually nurse-led. Complex wounds such as diabetes related foot ulcer, venous ulcers, pressure ulcers, surgical wounds, trauma-related wounds, wounds that do not heal as expected, chronic wounds and wounds that become infected all need different treatment plans but expertise in wound care varies, there can be limited direct involvement from tissue viability nurses and day-to-day care may be provided by health care assistants. It has been observed that treatment may change frequently for an individual with no documentation as to why this is the case (Guest et al. 2020) and caseload management, and prioritisation can be driven by logistics and staffing rather than wound treatment goals. There is wide variation in the standard of care for wounds across the UK (Gray et al. 2018). The National Wound Care Strategy Programme (NWCSP) commissioned by NHS England and NHS Improvement has identified accurate wound assessment, documentation and sharing of information between HCPs involved in wound care as being key components in improving wound care outcomes (NWCSP 2021).

2.1 Wound assessment

Wound assessment includes reliable measurement and documentation of the size of the wound and the type of tissue in the wound bed, assessing signs of infection and level of exudate and assessing the surrounding skin. Wounds should be measured at each change of dressing and the results documented, ideally in the patient's electronic health record (EHR) (Ousey & Cook 2012), although some community services in the UK still use mainly paper records.

There are several different methods for assessing the size of a wound. Planimetry, either manual or digital, involves tracing the outline of the wound onto acetate sheets. In manual planimetry, surface area is calculated by laying the acetate onto a grid and counting the number of squares in the wound outline. In digital planimetry, the wound outline is retraced onto a tablet and wound area is automatically calculated. Planimetry has been shown to be reliable and accurate, with digital planimetry being slightly more accurate (Jørgensen et al. 2016). However, the method involves contact with the wound which may increase risk of infection and patient discomfort. Alternatively, sterile, disposable paper rulers are used to measure the largest length and width of the wound, and this is the most common method for measuring wounds in Wales. Surface area is estimated by multiplying length by width, but this is only accurate for perfectly circular wounds and has been shown to overestimate wound area by up to 43% compared with digital planimetry. Consequently, mathematical formulae have been devised and multiplying length by width by 0.73 found to be more accurate for irregularly shaped wounds (Jørgensen et al. 2016). Wound depth is harder to measure in practice. Approximate measures of depth are obtained by probing the wound with a sterile swab (Ousey & Cook 2012), although volume can be measured reliability by injecting saline into a wound (Jørgensen et al. 2016). Both methods increase risk of infection. Assessment of the type of tissue in the wound bed, signs of infection and level of exudate are assessed qualitatively, and assessment tools such as the Wound Bed Score (WBS) are available (Falanga et al. 2006).

2.2 Digital imaging

In addition to measuring wounds, the NWCSP recommends that digital imaging of wounds is routinely used to support patient care (NWCSP 2021). Digital images can be taken by HCPs, using approved, ideally encrypted, devices, although images may also be taken directly by patients using their own devices. Images are securely uploaded to the patient's EHR and can be used for initial assessment; to monitor wound healing or changes in wounds; to support transfer of care to other HCPs; for multi-disciplinary team (MDT) wound review and to assist with remote care and to support patient engagement with self-care. The term 'store-and-forward' is sometimes used to describe the sending of images and information for remote viewing. It is different from real-time remote consultations through video or telephone conferencing, although store-and-forward technology may also be used to support these interactions. The NWCSP warns that patients must give valid consent for images to be taken and that privacy, dignity and safeguarding be upheld. Data must be stored in accordance with data protection legislation. Despite the recommendation that digital wound images should be used, the NWCSP reports that they are not yet routinely part of standard care in any healthcare setting, including home visits. There is no standardised practice across Wales regarding the use and storage photographs of wounds, although in some settings such as in-patients and specialised wound clinics the use of images of wounds is reported to be relatively common.

3. Health technology

Integrated digital wound management systems (DWMS) are specialist digital wound care solutions that combine three components:

- Three-dimensional imaging and automatic assessment
- Centralised digital dashboard
- Integration with individual patient EHRs

Systems use a point-of-care device capable of three-dimensional (3D) wound imaging combined with digital image processing that automatically measures the wound and wound bed tissue type. The device is either a stand-alone imaging device, or an application (app) used with a smartphone or tablet, or a combination of sensor, app, and tablet. Some devices require a fiducial marker to be applied to the skin near the wound to calibrate measurements and colour. Some devices make use of smartphone video capabilities. The automatic measurement of wounds is software or artificial intelligence (AI)-assisted, although there may be some human intervention necessary to indicate a rough wound outline and to correct errors. As well as imaging, the device is also used to record the complete patient assessment and treatment plan. At follow up visits, previous assessments and images are available, allowing HCPs to identify change and review wound images with patients.

The patient and wound assessment documentation is automatically uploaded to a centralised, secure, digital dashboard or portal. Via the dashboard, HCPs monitor changes to wounds over time and wound care specialists working remotely can provide expert input into treatment plans. The entire wound caseload can be reviewed, and patients can be prioritised depending on clinical need. The dashboard has the capability to send the assessments and treatment plans to individual patient EHRs.

There are other types of digital wound assessment devices that include two-dimensional (2D) photographs of wounds, often taken with a smartphone and stored with patient records or uploaded to a dashboard. The 2D systems do not have automatic wound measurement capability, although some systems allow the user to manually trace around the wound outline onto a touch screen for calculation of surface area, in common with digital planimetry. Other systems exist that do not use wound imaging but allow for upload of patient data to a dashboard for remote review. At our protocol stage we took expert advice and decided that the systems using 2D images or no images were different technologies from those using 3D imaging and software or AI-assisted wound assessment. As such, systems using 2D images were excluded. A full list of excluded systems can be found in the appendix.

HCPs who have used DWMS report that the systems could be used in any setting where wounds are managed. However, they may be most suitable for wounds managed in the community since wounds managed in acute settings may be too large or complex. The images can be taken and uploaded by any health professional and by patients and carers with appropriate training. Potential benefits of DWMS highlighted by manufacturers are that lower band HCPs can conduct wound assessments and be guided remotely, increasing capacity of higher band HCPs; that patients may be better able to self-manage their wounds; that resources and treatment can be better targeted to the right patient at the right time and that documentation improves and becomes more standardised.

At the time of this review, to our knowledge, two regulated systems are in use in the UK. Minuteful for Wounds (Healthy.io) is conducting pilot studies at different sites, including Swansea Bay University Health Board. Healthy.io reports that as of July 2023 there were 12 sites, and the device had been used by 1,278 clinicians to assess 18,689 patients with 42,382 wounds. A total of 188,159 assessments have been completed. The other DWMS, Insight (eKare) reports that it is working across a number rollout sites within UK. Studies are running in a selection of these sites with further pilot / rollouts scheduled for 2023. In addition, Insight has been used for wound assessment in clinical trials which compare different treatments for wounds. Four other devices were also identified from the literature. Two devices, Cares4Wounds (Tetsuyu Healthcare) and Wound Viewer (Omnidermal) are CE marked, and two, Swift Skin and Wounds (Swift Medical) and Tissue Analytics (Net Health) have approval in the US or Australia.

4. Clinical effectiveness

We searched for evidence that could be used to answer the review question: What is the clinical and cost effectiveness of integrated digital wound care management systems? We set a cut-off date of 2012 for the searches due to advances in medical technology that occurred around this time. We did not identify any guidelines, systematic reviews or randomised controlled trials. The evidence for this rapid review is drawn from a non-randomised comparative study, prospective and retrospective cohort studies and real-world evidence. For further details on the methodology used to identify evidence for this report, refer to Section 11.

4.1 Overview

We identified two distinct types of evaluation conducted for DWMS. One consisted of cross-sectional studies evaluating the reliability and/or concurrent validity (agreement with conventional measures taken at the same time) of the digital wound imaging and assessment (DWA) components of systems in healthcare settings. The other consisted of studies describing and evaluating use in practice of some, or all, of the components of DWMS.

4.1.1 Reliability and validity

We identified nine studies that evaluated test-retest and/or interrater reliability and/or concurrent validity. Eight (Aarts et al. 2023, Anghel et al. 2016, Chan et al. 2022, Fong et al. 2023, Swerdlow et al. 2023, Wang et al. 2017, Zoppo et al. 2020, Toygar et al. 2020) were prospective studies. Six of these were conducted in outpatient or wound clinics (Aarts et al. 2023, Anghel et al. 2016, Fong et al. 2023, Swerdlow et al. 2023, Wang et al. 2017, Toygar et al. 2020), one recruited both inpatients and outpatients (Chan et al. 2022) and one was conducted in a surgical ward (Zoppo et al. 2020). One retrospective study was identified (Jun et al. 2019) using data from medical records. Manufacturers varied across the studies, and eight were conducted by researchers who declared no conflict of interest. Insight was evaluated in five studies conducted in the Netherlands (Aarts et al. 2023), South Korea (Jun et al. 2019), Turkey (Toygar et al. 2020) and the USA (Anghel et al. 2016, Swerdlow et al. 2023). Cares4Wounds and Tissue Analytics were evaluated in Singapore by members of a vascular surgery service (Chan et al. 2022, Fong et al. 2023). Wound Viewer was evaluated in one study in Italy (Zoppo et al. 2020). Finally, Swift Skin and Wound was evaluated by founders of Swift Medical in a study conducted in Canada (Wang et al. 2017). We were unable to identify any studies evaluating reliability and validity for Minuteful for Wounds.

Only Wound Viewer (Zoppo et al. 2020) is a stand-alone imaging device, enabled with WiFi and 4G to allow for upload of images to a dashboard. The remaining systems run on different smartphones or tablets. Insight was evaluated either running on an iPad connected to a proprietorial sensor (Aarts et al. 2023, Anghel et al. 2016, Jun et al. 2019, Toygar et al. 2020, Swerdlow et al. 2023) or using the Insight CR app running on an iPhone 12 or 13 mini without a sensor (Swerdlow et al. 2023). Cares4Wounds (Version 1, build 1) (Chan et al. 2022) was evaluated on three different iPhones (8 Plus, 11 Pro and an XS) running iOS13. Tissue Analytics (Fong et al. 2023) was evaluated on an iPhone 11 running iOS13 and XiaoMi Mi Max2 smartphone, running Android 7.0. Swift Skin and Wounds (Wang et al. 2017) was evaluated on an iPhone 6 running iOS8.4. Smartphone and tablet technology and cameras have improved rapidly since 2012 and it is likely that the DWMS systems have also been updated during this period but only Chan et al. (2022) reported the DWMS version under evaluation.

The number of wounds ranged from 20 (Toygar et al. 2020) to 358 (Fong et al. 2023) and number of images from 20 (Toygar et al. 2020) to 2334 (Fong et al. 2023). One study gave no information on size of wounds (Anghel et al. 2016) and one reported a surface area range of 0.2 cm^2 to 60 cm^2 (Wang et al. 2017). In three studies (Chan et al. 2022, Fong et al. 2023, Swerdlow et al. 2023) wound surface area averaged between 3 cm^2 to 5 cm^2; in three studies (Aarts et al. 2023, Zoppo et al. 2020, Toygar et al. 2020) between 5 cm^2 to just over 10 cm^2, and one study (Jun et al. 2019) was conducted in patients with a mean wound size of 37 cm^2. It was not always clear which method was used to obtain the quoted surface areas. Five studies included people with wounds related to diabetes, or vascular or pressure ulcers (Chan et al. 2022, Fong et al. 2023, Jun et al. 2019, Wang et al. 2017, Zoppo et al. 2020, Toygar et al. 2020), one study was conducted in people with hidradenitis suppurativa (Aarts et al. 2023), one (Swerdlow et al. 2023) recruited people with any wound and included burns and one (Anghel et al. 2016) gave no information about wound type.

Study procedures were broadly similar for the prospective studies. Patients being treated for wounds were recruited into the study and one or more wounds were assessed using DWA devices by one or more raters in a healthcare environment. If concurrent validity was evaluated, wounds were also measured using a reference method such as manual measurements, or digital or manual planimetry. Wounds were typically imaged between three and seven times per study. The raters conducting the DWA were doctors, nurses, medical students, or research co-ordinators. Conventional measurements for concurrent validity were typically conducted by specialist wound nurses. For most studies it was unclear as to whether raters were blinded to each other, especially for interrater reliability, and it was unclear as to whether patients and raters were repositioned between measurements.

Three studies specifically excluded larger wounds (Aarts et al. 2023, Wang et al. 2017, Zoppo et al. 2020). One excluded wounds that were circumferential or in areas that were difficult to image and commented that the device could not delineate wound boundaries in low light and failed to measure wounds of less than 4 cm^2, but this is not reported in the results (Anghel et al. 2016). One study (Jun et al. 2019) reported that images were excluded if they were of poor quality or if they had non-valid measurements. One study (Toygar et al. 2020) excluded wounds with gangrene due to inability to delineate wound boundaries or inability to photograph. Three studies, conducted in mainly South East Asian populations, (Fong et al. 2023, Chan et al. 2022) reported that a small number of wounds required manual adjustment to wound boundaries, this was either due to poor colour contrast between wounds and darker skin tones, difficulty with delineating wounds of less than 1 cm^2 or were in areas with large amounts of skin contouring. Outcomes for reliability and concurrent validity are presented in sections 4.2 and 4.3 and Table A2 and Table A4.

4.1.2 Clinical effectiveness

Evidence for clinical effectiveness came from nine studies. We identified one non-randomised comparative very small (n=7) study (Lim et al. 2022), three prospective cohort studies, with historic comparators (Barakat-Johnson et al. 2022a, Wynn & Scholes 2022, Au et al. 2019b) and two single-arm prospective cohort studies (Barakat-Johnson et al. 2022b, Keegan et al. 2023). In addition, we were provided with real-world evidence from Minuteful for Wounds (Healthy.io. 2023) using data collected in the eight months after adoption at three UK sites in a single-arm retrospective cohort. A paper describing a small service evaluation in one of the sites was also included (Oliver et al. 2023). We also identified a time and motion study comparing time taken for wound assessment using DWA with time taken for conventional assessment (Mohammed et al. 2022). Table A1 gives details of study characteristics.

Studies were undertaken in the UK (Healthy.io. 2023, Wynn & Scholes 2022, Oliver et al. 2023), using Minuteful for Wounds; Australia (Barakat-Johnson et al. 2022a, Barakat-Johnson et al. 2022b) using Tissue Analytics; the USA using Swift Skin and Wound (Au et al. 2019b, Mohammed et al. 2022) and Minuteful for Wounds (Keegan et al. 2023); and Singapore using Cares4Wounds (Chan et al. 2022). Two studies (Barakat-Johnson et al. 2022a, Barakat-Johnson et al. 2022b) declared no conflict of interest, two (Wynn & Scholes 2022, Lim et al. 2022) declared that the devices used were provided by the manufacturer and the other studies declared that some, or all, authors were employees of the manufacturer. All systems ran on unspecified smartphones or tablets. We were unable to identify any studies evaluating clinical effectiveness for Insight eKare or Wound Viewer.

In the published studies, the number of participants recruited ranged from between nine (Lim et al. 2022) to "over 300" (Wynn & Scholes 2022), although one study (Au et al. 2019b) did not report numbers. The real-world evidence from Healthy.io. (2023) was obtained from treating 11,668 patients. One study (Keegan et al. 2023) was conducted in patients with diabetes related foot ulcers, one was monitoring pressure ulcers, one evaluated use in a podiatry service (Oliver et al. 2023) and the others were in patients with multiple different wound types or did not report wound-type. Setting varied. One study was conducted in inpatient units (Wynn & Scholes 2022) and one recruited a sample of HCPs to use DWMA with their patients and included both community and inpatients (Barakat-Johnson et al. 2022a). The remainder were conducted in community sites, including nursing homes, outpatients' clinics, and patients' own homes.

Study procedures varied. In all the studies, wounds managed under a DWMS protocol were imaged, automatically measured, and assessed at point-of-care and assessments were uploaded to a digital dashboard. In two studies patients, or their carers, took and uploaded the images themselves at dressing changes (Keegan et al. 2023, Barakat-Johnson et al. 2022b) and in one study some of the patients did so (Barakat-Johnson et al. 2022a). In all other studies an HCP imaged the wound. All studies, except for Mohammed et al. (2022), used the digital dashboard for remote wound review by HCPs with expertise in wound care and for caseload management. Oliver et al. (2023) specifically presented a service evaluation after instigation of remote reviews by a senior team using the dashboard facility. One study (Lim et al. 2022) reduced face-to-face visits from a wound specialist from once a week to once every two weeks as part of the intervention protocol. The device used also included an algorithm that offered advice on wound management, including use of generic dressings, cleansing solutions, additional skin products and the need for debridement. In three studies (Barakat-Johnson et al. 2022a, Barakat-Johnson et al. 2022b, Keegan et al. 2023) there was the facility for patients to directly contact their wound care team, using the app, outside of routine appointments. At least two studies (Barakat-Johnson et al. 2022a, Barakat-Johnson et al. 2022b) did not use automatic integration with EHRs, although assessments were added manually by the medical records department.

In two studies where patients used the DWMS device themselves, patients were excluded if they were unable to use a smartphone or access the system. Barakat-Johnson et al. (2022b) reported excluding 41% (n=168) of patients screened because they could not access the DWMS app. Keegan et al. (2023) did not report the number of patients excluded but seven (28%) participants were provided with a smartphone because their own was incompatible with the DWMS app. One ward-based study (Wynn & Scholes 2022) reported that ward staff experienced initial difficulties accessing the DWMS app due to compatibility issues with tablets that were available on the ward. It was not clear as to how the issues were resolved.

Only four studies had a comparator group. In those that did, usual care varied between studies. Lim et al. (2022) conducted a non-randomised comparison study in two nursing homes, one acting as control. In usual care, wounds were managed by the nursing home staff, with weekly assessment and recommendations from a wound specialist. Three studies employed a historic comparison group, using data from patients treated under usual care in the recent past. In

Barakat-Johnson et al. (2022a) usual care was a text-based platform for wound documentation, with 2D images stored separately and accessible by senior wound care nurse consultants only. In a ward-based study (Wynn & Scholes 2022) usual care was not well described but was provided by ward staff with support from a tissue viability service. 2D images were used but were reported as being difficult to access and documentation was reported as inconsistent. Au et al. (2019b) reported that usual care was to measure the wound using traditional ruler-based and drawing techniques, with pressure ulcer risk assessment recorded on a paper chart before being transferred to patients' EHR.

In addition to variation in study settings and procedures, there were variations in follow up times, which ranged from eight weeks to twelve months. There was little information about wound severity or treatment protocols, which also may vary between settings.

4.1.3 Overview of clinical effectiveness outcomes

Reported wound healing outcomes were complete closure of wounds, time to complete closure, wound healing rate, change in wound surface area, wound bed improvement and percentage of patients with pressure ulcers. We did not identify any studies that reported on resolution of infection, number of amputations, adverse events, length of hospital stay or quality of life.

There was limited comparative evidence for wound healing outcomes. Consequently, we sought further advice from experts on what other outcomes would indicate that DWMS could be an effective way of managing wounds. Table 1 shows an evidence map indicating the outcomes advised by experts and whether they were reported in the identified studies.

Table 1 – Evidence map for outcomes advised by experts

Advised outcome	Number of studies	References
Infection		
Number of patients with infection	0	N/A
Patient-reported outcomes		
Quality of life[1]	0	N/A
Pain score	0	N/A
Exudate	0	N/A
Acceptability		
Patient response rate / adherence[1]	Prospective cohort: 1	Keegan et al. (2023)
Retention rate and adherence over time	0	0
Patient satisfaction[1]	Prospective cohort: 2	Keegan et al. (2023) Barakat-Johnson et al. (2022b)
Resource use		
Hospital bed-days	0	N/A
Overall contact with HCPs[1]	Prospective cohort: 2	Barakat-Johnson et al. (2022b) Keegan et al. (2023)
Patient requests for appointments / advice[1]	0	N/A
Specialist / senior HCP input	Prospective cohort: 2	Wynn & Scholes (2022) Healthy.io. (2023)
Need for surgical intervention	0	N/A

Advised outcome	Number of studies	References
Time for wound assessment[1]	Non-randomised controlled study: 1 Time and motion study: 1 Qualitative report: 1	Lim et al. (2022) Mohammed et al. (2022) Au et al. (2019b)
Documentation		
Improvement in documentation[1]	Non-randomised comparison: 2 Qualitative report: 1	Barakat-Johnson et al. (2022a) Wynn & Scholes (2022) Au et al. (2019b)
Accuracy of wound assessment in documentation[1]	Qualitative report: 1	Au et al. (2019b)
Evidence that optimised wound care pathways / standardised practice are in use	0	N/A

[1]Identified in the PICO

Outcomes for clinical effectiveness are presented in sections 4.4 and 4.5 and Table 2 and Table 3.

4.2 Reliability outcomes

Six studies reported test-retest or inter-rater reliability. Test-retest reliability compared results obtained by the same rater, using the same device on the same wound. Inter-rater reliability evaluated results between raters, or between DWA apps running on different platforms such as different tablets, different smartphones, and on different operating systems. Results for surface area, depth and volume are reported below. Table A2 also includes results for width and length.

All studies used intra-class correlation statistics (ICC) to evaluate reliability and one (Aarts et al. 2023) presented Bland Altman plots and limits of agreement (LoA). Studies interpreted ICCs <0.5 as poor agreement, ≥0.5 to 0.75 as moderate agreement, ≥0.75 to 0.9 as good agreement and >0.9 as excellent agreement. Pre-defined acceptable LoA were not reported.

4.2.1 Test-retest reliability for surface area

Five studies (Aarts et al. 2023, Anghel et al. 2016, Chan et al. 2022, Fong et al. 2023, Swerdlow et al. 2023) evaluated test-retest reliability for surface area. All studies reported excellent test-retest reliability, with ICCs between 0.974 (95% CI: 0.969, 0.978) (Fong et al. 2023) to 0.998 (0.996, 0.999) (Aarts et al. 2023).

Aarts et al. (2023) reported wound sizes size from 2.5 cm^2 to 95.8 cm^2. The mean difference between measures and LoA were -0.35 (-2.9, 2.2) cm^2. A systematic bias of -0.03 cm^2 was reported, which was described as almost zero.

Swerdlow et al. (2023) examined the difference in mean surface area between tests and found no evidence for a difference ($p>0.05$).

4.2.2 Test-retest reliability for depth and volume

Anghel et al. (2016) evaluated test-retest reliability for depth and volume. Poor test-retest reliability was reported for depth (ICC: 0.360; 95% CI: 0.079, 0.588), but volume showed good reliability with an ICC of 0.888 (95% CI: 0.806, 0.937).

The authors commented that one rater was inconsistent with camera angles which may have contributed to poor reproducibility with depth. The device did not calculate volume from the depth measurement but used a depth-map of the whole 2D image, which explains why low reliability for depth did not automatically result in low reliability for volume.

4.2.3 Inter-rater reliability for surface area

Six studies (Aarts et al. 2023, Swerdlow et al. 2023, Anghel et al. 2016, Fong et al. 2023, Chan et al. 2022, Wang et al. 2017) evaluated inter-rater reliability, either between different raters or between the same DWA app running on different operating systems or different hardware.. All studies reported excellent agreement when testing between raters or between platforms. ICC ranged from 0.965 (95% CI 0.949, 0.977) (Chan et al. 2022) to 0.999 (95% CI 0.998, 0.999) (Anghel et al. 2016).

Aarts et al. (2023) reported a mean difference between measures and LoA to be -0.12 (-3.1, 2.9) cm^2. A systematic bias of -0.03 cm^2 was reported, which was described as almost zero.

Swerdlow et al. (2023) examined the difference in mean surface area between raters and found no evidence for a difference ($p>0.05$).

4.2.4 Inter-rater reliability for depth and volume

Anghel et al. (2016) evaluated inter-rater reliability for depth and volume. Moderate agreement between raters was reported for both depth (ICC: 0.649; 95% CI: 0.441, 0.791) and for volume (ICC: 0.696; 95% CI: 0.511, 0.820).

4.3 Concurrent validity outcomes

Concurrent validity for surface area was evaluated by comparing wound measurements by DWA with rule measurements and/or manual or digital planimetry in all studies, except two (Wang et al. 2017, Swerdlow et al. 2023). Anghel et al. (2016) evaluated concurrent validity for depth and volume, using a cotton swab for depth and saline solution for volume. Zoppo et al. (2020) evaluated concurrent validity for depth, using a cotton swab, and agreement for wound condition against a visual inspection. Studies used ICC statistics, correlations, concordance correlation coefficients (CCC), comparison of means, medians or distributions, coefficient of variance and Bland Altman LoA. ICC statistics and correlations were interpreted as for reliability. No studies used a pre-defined LoA.

Results for surface area, depth and volume are reported below. Table A4 also includes results for width and length.

4.3.1 Concurrent validity with ruler measurements for surface area

Aarts et al. (2023) reported excellent agreement (ICC: 0.916; 95% CI 0.857, 0.951).

Anghel et al. (2016) examined concurrent validity using correlations and reported a correlation of 0.996. However, a difference between median surface area when measured by DWA compared with ruler measurement was observed (exact figures not reported, $p<0.001$).

4.3.2 Concurrent validity with planimetry for surface area

Aarts et al. (2023), Chan et al. (2022), Fong et al. (2023) and Toygar et al. (2020) reported good to excellent agreement for all devices tested. ICCs ranged from 0.799 (95% CI 0.678, 0.866) (Fong et al. 2023) to 0.987 (95% CI 0.977, 0.992) (Aarts et al. 2023). Toygar et al. (2020) also reported CCCs of 0.925 (95% CI 0.825, 0.968) for manual planimetry and 0.926 (95% CI 0.826, 0.969) for digital planimetry.

Aarts et al. (2023) also presented Bland Altman plots. Wounds were quoted as ranging in size from 2.5 cm^2 to 95.8 cm^2. The mean difference between measures and LoA were 0.97 (-6.1, 8.1) cm^2. A systematic bias of -0.11 cm^2 was reported, which was described as close to zero.

Toygar et al. (2020) also presented Bland Altman plots and LoA. Wounds ranged in size from 0.10cm^2 to 23.74cm^2. The mean difference between measures and LoA were -0.2 (-5.5, 5.2) cm^2 for manual planimetry and 0.1 (-1.0, 1.3) cm^2 for digital planimetry. The authors report that there was some evidence for wider variation between measurements for wounds that were larger than 10cm^2, due to difficulty in photographing the entire wound area.

Anghel et al. (2016) examined concurrent validity using correlations and reported a correlation of 0.997. No difference between median surface area when measured by DWA vs measured by planimetry was observed (exact figures not reported, $p=0.911$).

Jun et al. (2019), in a retrospective study with concurrent images for planimetry and DWA obtained from medical records, reported no evidence for a difference in mean surface area between measures (planimetry: 37.14 (41.47) cm^2 vs DWA: 36.95 (39.54) cm^2, $p=0.838$). Bland Altman plots were presented. The mean difference between measures and LoA were 0.19 (-8.91, 9.29) cm^2.

Zoppo et al. (2020), reported surface area of 5.5 (2.9, 14.1) cm^2 for planimetry vs 6.1 (2.9, 14.5) cm^2 for DWA. A statistical goodness-of-fit model comparing obtained Weibull distribution curves for both measures showed agreement between methods ($p>0.9$).

4.3.3 Concurrent validity for depth and volume

Jun et al. (2019) reported a difference in mean wound depths measured with a cotton swab and with DWA (cotton swab: 1.53 (1.46) cm vs 0.84 (0.75) cm, $p<0.001$) and between mean volumes measured with saline solution and DWA (saline: 88.92 (145.06) cm^3 vs 20.13 (31.73) cm^3, $p=0.005$). For maximum depth, mean difference and LoA were 0.69 (-0.78, 2.16) cm and for volume, 68.79 (-157.04, 294.63) cm^2. LoA were reported as unacceptably wide, given the size of the wounds.

Zoppo et al. (2020) reported median depths of 1.9 (1.0, 3.0) cm for a probe vs 2.1 (1.7, 3.2) cm for DWA. The distribution was reported as being too irregular to allow comparison to be made.

4.3.4 Concurrent validity for wound condition

Zoppo et al. (2020) evaluated Wound Bed Scores (WBS) (Falanga et al. 2006) produced by a DWA device from the images taken with scores obtained from blinded HCP assessment. An overall agreement of 96% was reported.

4.4 Wound healing outcomes

4.4.1 Complete closure, time to complete closure and wound healing rate

Two studies with eight-week follow-ups reported number of patients experiencing wound closure at the end of the study. Lim et al. (2022) reported that two (40%) patients in the intervention group (n=5) experienced wound closure and none of the patients in the control group (n=2). Due to the size of the study, it was not possible to draw conclusions about comparative effectiveness. In a single-arm study of twenty-five patients, Keegan et al. (2023) reported that three (12%) patients experienced wound closure.

Barakat-Johnson et al. (2022b) conducted a study with a seven-month follow-up and reported number of wounds that closed in 12-weeks and in 24-weeks. Nineteen (31%) wounds closed in 12-weeks and a further seven (12%) closed by 24-weeks, giving a total number of wounds closed as 26 (43%). Median time to complete closure was reported as 66 (95% CI: 56, 88) days. Mean wound healing rates, for all included wounds (n=61) were reported for different wound types and ranged from 0.011 (0.006) cm/day for diabetes related foot ulcers to 0.04 (0.034) cm/day for other wounds.

Healthy.io. (2023), in an eight-month real world evaluation involving 10,879 wounds, reported percentage of wounds that closed in 12-weeks from the first three months after adoption compared to six-to-eight-months post-implementation. For vascular wounds, rates of complete closure improved from 17% to 28%, $p<0.0001$. For diabetes related wounds, rates changed from 18% to 21% but there was no evidence for improvement ($p>0.05$) and there was no evidence for change in non-chronic wounds (24% to 24%, $p>0.05$). The study authors say that changes in healing rates rate for non-chronic wounds were not expected.

4.4.2 Change in wound surface area

Lim et al. (2022) reported that three (60%) patients in the intervention arm experienced an increase in wound size and the two patients in the control arm experienced a decrease in wound size.

Barakat-Johnson et al. (2022a) examined a sub-set of the intervention group that had more than one wound scan (wounds=132). The authors reported that 31 (23.5%) wounds increased in size, with a mean increase of 81% and 101 (76.5%) wounds decreased in size, with a mean decrease of 54% during the study period, which was defined as up to point of discharge for inpatients and three months after enrolment for outpatients/community. No comparative data were available for standard care.

Keegan et al. (2023) reported a mean reduction in surface area of 7.67 cm^2 over eight weeks.

Barakat-Johnson et al. (2022b) reported that, in wounds that had not healed by the end of the study (n=35), six (17%) increased in size by a mean of 25.5% and 29 (83%) had decreased in size by a mean of 51.9%.

Oliver et al. (2023) identified wounds that were deteriorating and compared those reviewed remotely by a senior team via the DWMS dashboard with those that were not reviewed by a senior team. They reported that 56% of reviewed wounds improved compared to 50% of wounds that were not reviewed in this way.

4.4.3 Wound bed improvement

Lim et al. (2022) used the Wound Bed Score (Falanga et al. 2006) to estimate changes to the condition of the wound. A mean improvement in scores of 8.7% was reported in the intervention group, compared to a 4.7% improvement in the control group. Due to the size of the study, it was not possible to draw conclusions about comparative effectiveness.

4.4.4 Percentage of patients with pressure ulcers

Au et al. (2019b), evaluated the effect of service improvements, including DWMS adoption, on prevalence of pressure ulcers in nursing home residents. Reporting periods were between the second quarter of 2015 and the fourth quarter of 2016, prior to adoption, and the first quarter of 2018, one year after adoption. In long stay patients, median prevalence prior to adoption vs after adoption was 11.1% vs 5.3% and in short stay patients this was 0.5% vs 0%. In addition to adoption of DWMS there were substantial other improvements to the service. Consequently, it was not possible to draw conclusions about the comparative effectiveness of DWMS alone.

Table 2 – Wound healing outcomes

Outcome	Evidence source	Study design (participants/wounds)	Absolute effect	Relative effect [95% CI] (interpretation)	Comments
Complete closure in ≤8wks	Lim et al. (2022)	Non-randomised comparative study (n=7; wounds NR)	Patients (n (%)) experiencing wound closure: DWMS: 2 (40%) Comparator: 0 (0%)	NR	Descriptive statistics only
	Keegan et al. (2023)	Prospective cohort (n=25; wound scans=179)	Patients (n (%)) experiencing wound closure: 3 (12%) patients No comparator	NA	Descriptive statistics only
Complete closure in ≤12wks	Healthy.io. (2023)	Retrospective cohort (n=nr; wound=10,879)	Wounds (%) healed in ≤12wks Time after adoption: 0-2m vs 3-5m vs 6-8m Vascular wounds: 17% vs 21% vs 28% Diabetes related wounds: 19% vs 17% vs 21% Non-chronic wounds: 24%; 25%; 24% No comparator	Vascular wounds +65%, [CI nr] p<0.001 **Improvement over time** Diabetes related wounds: +13% [CI, nr], p>0.05 **No difference**	No adjustment for covariates
	Barakat-Johnson et al. (2022b)	Prospective cohort (n=51; wounds=61)	Wounds (%) healed in ≤12wks: 19 (31%) By wound type: Vascular ulcers: 3/19 Diabetes related foot ulcers: 8/17 Complex surgical wounds: 6/14 Other wounds: 2/7 Wounds (%) healed in >12 to ≤24wks: 7 (12%) By wound type: Diabetes related foot ulcers: 3/17 Complex surgical wounds: 4/14 Total wounds healed: 26 (43%) No comparator	NA	Descriptive statistics only
Wound healing rate	Barakat-Johnson et al. (2022b)	Prospective cohort (n=51; wounds=61)	Mean (SD) wound healing rate (cm/d) Vascular ulcers: 0.014 (0.008) Diabetes related foot ulcers: 0.011 (0.006)	NA	

Outcome	Evidence source	Study design (participants/wounds)	Absolute effect	Relative effect [95% CI] (interpretation)	Comments
			Complex surgical wounds: 0.019 (0.013) Other wounds: 0.04 (0.034) No comparator		
Time to complete closure	Barakat-Johnson et al. (2022b)	Prospective cohort (n=nr; wounds=26)	Median time to healing (days) DWMS: n=66 (95% CI: 56, 88) No comparator	NA	Descriptive statistics only
Change in wound surface area	Lim et al. (2022)	Non-randomised comparative study (n=7; wounds NR)	Patients experiencing an increase in size: DWMS: n=3 (60%) Comparator: n=0 (0%) Patients experiencing a reduction in size: DWMS: n=0 (0%) Comparator: n=2 (100%)	NR	Descriptive statistics only
	Keegan et al. (2023)	Prospective cohort (n=25; wound scans=179)	Mean (SD) reduction (cm^2) DWMS: 7.67 (9.72), p=0.005 Mean decrease 41.6% (SD, 15.8%) No comparator	NR	No adjustment for covariates
	Barakat-Johnson et al. (2022a))	Prospective cohort (42% of DWMS group only) (n=52; wounds=132)	Increase in wound size area (wounds) DWMS: wounds=31 (23.5%) Mean increase (%) 81.0 (83.2) No comparator Decrease in wound size area (wounds) DWMS: wounds=101 (76.5%) Mean decrease (%) DWMS: 54.0 (31.6) No comparator	NR	Descriptive statistics only
	Barakat-Johnson et al. (2022b)	Prospective cohort (n=nr; wounds=35)	Increased in size (wounds): 6 (17%) Mean (SD) increase (%): 25.9 (25.8) Decreased in size (wounds): 29 (83%)	NR	Descriptive statistics only

Outcome	Evidence source	Study design (participants/wounds)	Absolute effect	Relative effect [95% CI] (interpretation)	Comments
		Only including wounds that had not healed by the end of the study	Mean (SD) reduction (%): 51.9 (21.1) No comparator		
	Oliver et al. (2023)	Prospective cohort (n=nr; wounds=nr)	Proportion of improved wounds DWMS +senior review = 56% Comparator (DWMS +no review) = 50% Proportion of deteriorating wounds DWMS +senior review = 44% Comparator (DWMS +no review) = 50%	NR	Descriptive statistics only
Wound bed improvement	Lim et al. (2022)	Non-randomised comparative study (n=7; wounds NR)	Mean (SD) improvement in WBS (%) DWMS: 8.7 (7.2) Comparator: 4.2 (3.5)	NR	Descriptive statistics only
Patients with pressure ulcers (%)	Au et al. (2019b)	Prospective cohort (n=nr; wounds=nr)	Percentage of patients with pressure ulcers during recording period (median) Standard care vs DWMS +skin integrity coordinator Long stay patients. 11.11% vs 5.33% Short stay patients 0.45% vs 0%	NR	Descriptive statistics only

Abbreviations: d=days; DWMS=digital wound management system; m=months; N/n=number; NA=not applicable; NR=not reported; SC=standard care; TVN=tissue viability nurse; UC=usual care; WBS=Wound bed score (Falanga score); wks=weeks

4.5 Other outcomes

4.5.1 Patient satisfaction and adherence

Patient satisfaction was measured using study specific surveys in two studies where patients or carers took and uploaded wound images.

Keegan et al. (2023) reported that 17 (68%) participants completed the survey at the end of the study. Across the whole cohort (n=25) 64% ‘agreed’ or ‘strongly agreed’ that DWMS was useful and 56% “agreed” or “strongly agreed” that it was easy to learn.

Barakat-Johnson et al. (2022b) introduced DWMS to patients who were receiving standard wound care. Patients were asked to complete a patient satisfaction survey at baseline before DWMS introduction, and at the end of the study. The second survey also included questions about usability and acceptability of the digital app. A five-point Likert scale, where five represented a high score, was used. Mean reported satisfaction on the digital app for ease of use, access to wound care service, ease of communication, self-empowerment, supporting face-to-face consultation and recommending the app were 4.0 or over, although reduced travel to see the specialist scored 3.6. Comparisons were made between overall perception of care services, access to wound care services, ease of communication, ease of travel and self-empowerment. Scores ranged from 3.8 (ease of travel and seeing the specialist) to 4.8 (perception of services) before introduction, with no difference in scores by the end of the study. Preference for face-to-face consultation was 4.5 at baseline and 4.3 at the end.

Keegan et al. (2023) also reported on patient adherence. Patients were asked to submit an image at least once a week over eight weeks. Five (20%) patients submitted all images, with seven (28%) submitting 75% or more of images. Seven (28%) submitted no more than 25% of images and were considered non-adherent. Non-adherence was due to communication difficulties and lack of availability of carers for the imaging. The mean (SD) number of images per patient per week was 0.72 (0.63).

4.5.2 Wound assessment time

Lim et al. (2022) reported resource use, in terms of mean time to assess a wound. Nursing home staff took 27.2 (9.9) minutes using DWMS vs 28.8 (7.6) minutes in the control nursing home. The wound specialist took 48.5 (11.4) minutes using DWMS vs 61.4 (9.7) minutes for control patients.

Mohammed et al. (2022) conducted a time and motion study in 91 patients, with 115 wounds. The time taken by five nurses to assess and document the same wound using DWMS was compared with time taken to use a paper ruler combined with 2D images. Overall, total time for all wounds took 2 hours and 44 minutes for DWMS and 5 hours 31 minutes for standard measures. Mean time to assess individual wounds, without upload time 55 seconds for DWMS compared to 2 minutes 53 seconds for standard measures. When time to upload to the dashboard was included DWMS time increased to 1 minute 52 seconds.

Au et al. (2019b) reported qualitative results that use of the DWMS reduced weekly data entry time from up to 6 hours to "the order of minutes".

4.5.3 Specialist staff input

Wynn & Scholes (2022), in a ward-based study, reported on the number of referrals to the tissue viability service that resulted in a visit from a tissue viability nurse. There was a reduction of 10%, from 73% to 63%, although no statistical comparisons were made. The authors indicate that this drop was due to improved triage made possible by improved access to wound images and the use of a centralised dashboard.

Healthy.io. (2023) reported specialist input in terms of the percentage of assessments conducted by 'unregistered clinicians' (assumed to be mainly health care assistants). In the first three months after adoption 32% of assessments were conducted by 'unregistered clinicians' compared with 43% by eight months. The authors suggest that this change gave 'registered clinicians' more time to focus on more complex wounds.

4.5.4 Contact with HCPs

Two studies reported on contact with either HCPs or the study team. In both studies the patients took images of wounds themselves and uploaded them for remote review.

Barakat-Johnson et al. (2022b) reported contact with HCPs as occasions of service, defined as any examination, consultation, treatment, or any other service provided. Data were collected and recorded by the DWMS. Over 229 days, the total number of contacts for 51 participants was 828. On average, each participant was reported as receiving one HCP contact every 4.4 days.

Keegan et al. (2023) reported the mean number of calls made per patients to remind them to upload their wound image was 2.28 over eight weeks. In addition, the mean number of technical calls initiated or received by patients was 6.32. No details were provided as to the nature of the technical calls.

4.5.5 Documentation

Barakat-Johnson et al. (2022a) compared the number of dressing changes where wound assessment was recorded between DWMS and usual care in a five-month study. Wound size was recorded in 100% of wounds managed using DWMS, compared to 8.3% in the previous four months, an improvement of 91.7% (95% CI: 86.2 to 97.2). Recording of pain, exudate, odour, and the wound management schedule also all improved by between 6.1% (wound management schedule) to 55.2% (exudate). The number of dressing changes where two or more items were recorded improved from 24.0% to 93.5%.

Wynn & Scholes (2022) described completion of documentation on referral to the tissue viability service in a seven-month ward-based evaluation of DWMS. Usual care data from the three months before DWMS adoption were used as a comparator. No statistical comparisons were made but there appeared to be a 11% reduction in the number of referrals containing a complete wound assessment and treatment plan, from 43% to 32%; a 37% increase in the number of referrals with wound photography, from 23% to 60%, although there was also a 48% increase in available of images taken by medical illustrations in the same period.

Au et al. (2019b) reported qualitative results indicating that use of Swift Skin and Wound improved documentation and wound management. Nurses were able to survey all wounds, which was not previously possible, and the accuracy of wound assessment and completion of documentation improved. Progress could be tracked using the images, which were also used to increase understanding of treatment for patients, family members and other stakeholders. The ability to share wound photographs remotely with specialists in wound care was also reported to improve treatment.

Table 3 – Other effectiveness-related outcomes

Outcome	Evidence source	Study design (participants/wounds)	Absolute effect	Relative effect [95% CI] (interpretation)	Comments
Patient satisfaction	Keegan et al. (2023)	Prospective cohort (n=25; wound scans=179)	Post intervention "Agreed or strongly agreed": DWMS was useful = 64% Easy to learn = 56% Scan time was reasonable = 64% Using it increased responsibility for health = 56%	N/A	Descriptive statistics only
	Barakat-Johnson et al. (2022b)	Prospective cohort (n=69; wounds = 61)	Pre- (n=55) vs post- (n=44) intervention Perception of care services: 4.8 vs 4.9 Timely access to wound care services: 4.6 vs 4.8 Ease of communication with wound specialist: 4.6 vs 4.7 Ease of travel and seeing the wound specialist: 3.8 vs 3.8 Self-empowerment and confidence to manage own wounds: 4.6 vs 4.7 Preference for face-to-face consultation: 4.5 vs 4.3 For DWMS: Ease of use: 4.2 Timely access to service: 4.0 Ease of communication with specialist: 4.0 Reduced travel: 3.6 Self-empowerment and confidence in self-management: 4.0 Supporting face-to-face communication: 4.4 Would recommend: 4.5	NR	Likert scale: 1 = "strongly disagree" to 5 = "strongly agree". Descriptive statistics only No statistical comparisons made
Patient adherence	Keegan et al. (2023)	Prospective cohort (n=25; wound scans=179)	Patient engagement (n (%)) 100% weekly scans: 5 (20%) ≥75% weekly scans: 7 (28%) ≥50% weekly scans: 3 (12%) ≥25% weekly scans: 3 (12%) <25% weekly scans: 7 (28%) Mean (SD) number of scans submitted per patient per week = 0.72 (0.63)	NR	Descriptive statistics only
Wound assessment time	Lim et al. (2022)	Non-randomised controlled (n=7; wounds NR)	Mean (SD) time to assess wounds/patient (mins) DWMS vs Standard care	NR	Descriptive statistics only

Outcome	Evidence source	Study design (participants/wounds)	Absolute effect	Relative effect [95% CI] (interpretation)	Comments
			Nursing home staff during dressing changes: 27.2 (9.9) vs 28.8 (7.6) Wound specialist during visit: 48.5 (11.4) vs 61.4 (9.7)		
	Mohammed et al. (2022)	Time and motion study (n=91; wounds=115)	Total time for assessment DWMS vs UC 2hrs 44mins vs 5hrs 31mins	DWMS = 54% faster (95% CI NR)	p value nr
			Total mean (SD) measurement time per wound (without upload) DWMS vs UC 55secs (26secs) vs 2 minutes 53secs (38secs), p<0.001	DWMS = 79% faster (95% CI NR)	
			Total mean (SD) workflow time per wound (includes) upload: DWMS vs UC 1min 52secs (26secs) vs 2mins 53secs (38secs), p<0.001	NR **Favours DWMS**	
			Proportion of wounds measured on first attempt: DWMS vs Standard care 106 (92.2%) vs 87 (75.7%), p<0.004	NR **Favours DWMS**	
Specialist input	Wynn & Scholes (2022)	Prospective cohort (n="over 300"; wounds="over 800")	Referrals resulting in visit by TVN: SC vs DWMS 73% (77/105) vs 63% (153/241)	-10%, **Favours DWMS** (Represents improved triage)	p value nr
	Healthy.io. (2023)	Prospective cohort (n=nr; wound=10,879)	Percentage of assessments conducted by "unregistered clinicians": At 3 months after adoption: 32% At 6 months after adoption: 43%	NR **Favours DWMS**	
Contact time	Barakat-Johnson et al. (2022b)	Prospective cohort (n=51; wounds = 61)	Contact with HCPs during the study (over 229 days): Total number of contacts: 828 Average per participant: One HCP contact every 4.4 days. No comparator	NR	

Outcome	Evidence source	Study design (participants/wounds)	Absolute effect	Relative effect [95% CI] (interpretation)	Comments
	Keegan et al. (2023)	Prospective cohort (n=25; wound scans=179)	Mean (SD) number of calls per patient during 8-week study period. • Reminder calls from study team: 2.28 (2.25) • Technical calls to or from Healthy.io team: 6.32 (5.18) No comparator	NR	No explanation given for technical calls.
Completion of documentation	Barakat-Johnson et al. (2022a)	Non-randomised comparison (n=297; wounds=427)	UC vs DWMS N (%) of dressing changes recording: • Pain: 80 (8.6%) vs 185 (41.4%), p<0.001 • Wound size: 78/935 (8.3%) vs 447/447 (100%), p<0.001 • Exudate: 298 (31.9%) vs 390 (87.2%), p<0.001 • Odour: 17 (1.8%) vs 181 (40.5%), p<0.001 • Wound management schedule: 278 (30.2%) vs 162 (36.3%), p=0.02 • ≥2 items documented: 244 (24.0%) vs 418 (93.5%), p<0.001	Improvement in documentation (%): • Pain: 32.8 (28.4, 37.2) • Wound size: 91.7 (86.2, 97.2), • Exudate: 55.2 (49.7, 60.9) • Odour: 38.7 (34.8, 42.7) • Schedule: 6.1 (0.8, 11.4) • ≥2 items: 69.5 (63.9, 72.1) **Favours DWMS**	
	Wynn & Scholes (2022)	Prospective cohort (n="over 300"; wounds="over 800")	UC vs DWMS Referral contained complete assessment and treatment plan: 43% (59/136) vs 32% (59/182)	-11% **Favours UC**	p value nr
			Referral contained wound image: 23% (31/136) vs 60% (144/241)	+37% **Favours DWMS**	p value nr
			During implementation period, images were also available from medical illustrations for 48% (115/241)	+25% **Favours DWMS**	p value nr

Abbreviations: d=days; DWMS=digital wound management system; m=months; N/n=number; NA=not applicable; NR=not reported; SC=standard care; TVN=tissue viability nurse; UC=usual care; WBS=Wound bed score (Falanga score); wks=weeks

4.6 Ongoing studies

We identified one registered ongoing randomised controlled trial, described in Table 4. In addition, the Topic Proposer has indicated that a retrospective comparison of wound healing outcomes before and after adoption of DWMS conducted in the US is planned. Publication is estimated as being 2023/2024. A real-world study undertaken by the Skin Integrity Institute Cambridge, using Minuteful for Wounds is planned for publication in January 2025. eKare has reported that a study describing a non-randomised comparison feasibility study has been prepared for publication. The study examined acceptability, adherence, and feasibility of use of Insight in 59 surgical patients discharged with wounds or drains.

Table 4 – Summary of ongoing primary studies

Study information	Status	Research question and outcome measures
Registration: NCT05579743 **Country:** USA **Target recruitment**: 120 **Follow-up:** 12 weeks **Study completion date:** 20.06.2024	Recruiting **Last updated:** 28.06.2023	Can a smartphone mobile application designed to capture wound measurements and analyse wound tissue in real time be a practical solution for wound management? **Population:** Adults with diabetes related foot ulcers **Intervention:** Use of DWMS by patients for wound assessment once a week. Monthly face-to-face follow up. **Comparator:** Usual care, with biweekly follow up in outpatients. **Primary Outcome Measure:** Proportion of participants who successfully complete a weekly wound scan. **Secondary Outcome Measure:** None specified

4.7 Certainty of the evidence

4.7.1 Reliability and concurrent validity

- Some studies excluded images due to quality, or manually adjusted images where the wound boundaries were poorly delineated, potentially introducing bias. When used in routine practice, the reliability and accuracy of DWA may be lower than that obtained in research settings.
- There are uncertainties around reliability and accuracy of DWA for small or very large wounds, for wounds in skin folds or on curved areas of the body, and in patients with darker skin tones.
- All the included studies were conducted in a healthcare setting, where the position of the patient and the lighting could be optimised and kept constant. Images were taken by medically trained staff or researchers. The results obtained in these controlled environments may not be generalisable to wound imaging conducted in a patients' own home, especially where images are taken by patients or their carers.
- One study suggested that 24% of wound images could not be used. Failure of DWMS could mean that manual measurements need to be taken, which may increase staff time.

- Studies using Bland Altman LoA did not report pre-specified acceptable levels of agreement between different measurement methods. Experts contacted by HTW observed that existing methods for measurement, especially rulers, are prone to errors. Despite this, it was thought that correlation between the reference measure and DWA was important and as a ‘rule of thumb’ correlations of >0.7 could be considered acceptable agreement. One expert suggested that acceptable LoA should be <0.5cm^2. Standardising the approach to using DWMS across Wales to ensure validity and consistency was advised.
- There are uncertainties around the ability of DWA to measure wound depth and volume. One expert queried as to whether in cavity wounds, the systems were able measure areas of undermining or tracking or recognise bone, tendon, or muscle at the base.
- Five of the included studies were conducted in Southeast Asian populations, limiting the generalisability for a Welsh population.
- Independent reliability or concurrent validity data was not available for all the identified systems. Two experts commented that it was important that this information was available to evaluate the quality of the systems.

4.7.2 Clinical effectiveness

- Studies that reported on aspects of clinical effectiveness were pilot or feasibility studies that aimed to test whether implementation of DWMS was practical, so most lacked comparisons and used descriptive statistics only.
- The shorter follow up periods do not allow for assessment of longer-term outcomes.
- The use of historic controls may result in methodological variation in the measurement of outcomes, and it is not always clear as to how patients were selected for inclusion.
- The largest comparative study with wound healing outcomes, Au et al. (2019b), adopted DWMS at the same time as implementing significant service improvements, including employing a skin integrity coordinator with resources available to bring in other measures aiming to prevent pressure ulcers. However, there is some qualitative evidence from this study that use of Swift Skin and Wound improved documentation, wound management, and data entry time.
- We found evidence that documentation of wound measurements and presence of wound images improved. Experts thought that improved documentation was an important outcome for DWMS. It was suggested that more consistent documentation could be used to audit services and ensure optimal treatment pathways were being used. However, there was evidence from one study that documentation of treatment plans decreased after adoption of DWMS. It is uncertain as to whether the automatic wound assessments produced by the app could displace full wound assessment and documentation of treatment plans in routine care.
- Reproducibility is limited due to limited description of usual care and methods of treating wounds of different types. There was also some uncertainty as to how exactly DWMS was adopted into different settings.
- The heterogeneity in study design and procedures, potential for bias within studies, limited number of comparative studies, small sample sizes, use of descriptive statistics, and lack of control for confounders such as wound severity or any comorbidities, contribute to the uncertainty in the conclusions drawn by this report.

5. Cost effectiveness

5.1 Economic literature review

We conducted a rapid systematic literature review to answer the following research question: what is the cost effectiveness of integrated digital wound care management systems compared to standard care? Appendix 3 summarises the selection of articles for inclusion in the evidence review. The titles and abstracts of 2,660 records identified in the search for this research question were screened and 19 records were deemed potentially relevant. The full texts of these studies were reviewed against the inclusion/exclusion criteria and all studies were excluded.

Although many of the studies were assessing digital interventions for wound management, the majority of studies (Arora et al. 2017, Fasterholdt et al. 2018, Nair 2018, Stern et al. 2014, Summerhayes et al. 2012, Abu-Sheasha et al. 2020, Gamus & Chodick 2019) (n = 7) were excluded as they were not the exact intervention of interest, for example, they did not include 3D imaging, or images that were taken were inspected by medical professionals, rather than being interpreted using AI. Five studies (Chan & Lo 2020, Kostovich et al. 2022, Niknamian 2019, Shi et al. 2022, Tricco et al. 2015) were excluded as they were systematic reviews, and four studies (Au et al. 2019a, Barakat-Johnson et al. 2022b, Mohammed et al. 2022, Téot et al. 2020) did not mention costs. One study was non-comparative (Au & Wang 2019), one was a summary of Medicare spending on wounds in general (Nussbaum et al. 2018) , and the final study was excluded as it was conducted in a non-OECD country (Lim et al. 2022).

However, as Lim et al. (2022) does provide limited cost data, a brief overview will be provided. The study was conducted in Singapore and compared the use of an integrated DWMS (Cares4Wounds) to conventional care in a nursing home environment, to determine whether less clinician visits would be required under the new intervention. 9 patients were recruited into the study, however 2 patients were transferred to hospital during the study, and so data was only collected on 7 patients. The intervention and control group were made up of patients from 2 separate nursing homes, consisting of 5 and 2 patients, respectively. Patients were followed up for a period of 2 months, and outcomes such as wound healing rate, time taken for wound assessment, useability and travel time to the nursing home were recorded. Consulting time and travel costs were combined and translated into an average cost of a clinician visit.

Results of the analysis found that the rate of improvement in wound healing, measured by the Falanga score, was higher in the intervention group than the control group. Time spent per patient during each visit by the clinician was reduced by 12.9 minutes, however there were minimal differences in the time spent per patient by the nursing home staff for standard wound inspection and dressing changes. This translated to average costs of $493.65 per patient in the intervention group, compared to $1317.95 per patient in the control group over the 2-month period, a total saving of $824.30. However, it should be noted that no statistical tests have been performed on these results due in part to the low patient numbers.

This study is considered as having major limitations, most notably the low patient numbers, meaning that no conclusions can be drawn from results of the study, and statistical significance cannot be calculated. It is noted in the study that COVID-19 seriously affected recruitment into the study, and that a higher sample size had been planned. In addition, patients were only followed up for 2 months, meaning long term outcomes are not available from the study. The study was a non-randomised trial, with differing care homes acting as control and intervention groups; this could have impacted results as standard of care could have differed slightly between the care homes. In terms of the costs, the study only included consultant costs of the clinician and travel time, and does not include other costs, such as nurse costs, training, installation, or other resource use. Finally, the study is limited to use in a care home setting and so we cannot draw conclusions from other settings, such as hospital or community.

5.2 HTW cost analysis

Clinical and economic evidence on integrated DWMS is minimal, and identified resource use data is limited to information on travel time and restricted information on clinician time. As such, a full economic analysis was not deemed to be feasible in this case.

A limited cost analysis has been conducted based on the cost of the device and resource use data presented in Mohammed et al. (2022). In their analysis, an integrated DWMS was found to reduce the average time to complete a full wound assessment by 1.01 minute when compared to using manual methods.

Using data provided by Healthy.io, it was calculated that integrated DWMS could cost around £17 per device, per week. Based on an average time saving of 1.01 minute when using DWMS, the number of assessments required per NHS staff band was calculated in order for no additional costs to be realised. This is provided in Table 5.

Table 5 – Required assessments with digital systems per week

NHS Banding (Jones et al. 2022)	Cost per hour	Cost per minute	Number of assessments required
Band 5	£46	£0.77	22
Band 6	£57	£0.95	18
Band 7	£68	£1.13	15
Band 8a	£78	£1.30	13
Band 8b	£91	£1.52	11
Band 8c	£107	£1.78	9
Band 8d	£127	£2.12	8
Band 9	£152	£2.53	7
GP Cost	-	£3.76	4

Data on areas currently using Minuteful for Wounds has been used to calculate the actual number of weekly assessments which have been conducted using the device per healthcare professional (assuming a licence is provided per healthcare professional), Table 6. If the number of assessments currently being conducted with integrated DWMS is assumed to be reflective of the number which would be likely if the device were to be adopted for use in Wales, it is unlikely that use of the device would translate to cost savings based on the time saving of 1.01 minute for time to complete a full wound assessment.

It should be noted that the cost analysis only considers the effect of DWMS on the time required to complete a full wound assessment and does not consider other resource use data, such as contacts with healthcare professionals. The cost analysis does not consider the effect of DWMS on outcomes other than resource use, such as wound healing outcomes.

Table 6 – Number of assessments per week in areas currently using digital systems

Health Board / ICB	Months in use	Number of licenses	Total number of assessments	Assessments per week per license
Swansea	16*	240	44,285*	3
Livewell South	24	180	74,694	4
North Cumbria	19	235	18,378	1

ICB – integrated care board
* This excludes a rollout period of 6 months – the number of assessments provided includes the rollout period and so this is an optimistic scenario.

6. Organisational considerations

Experts contacted by HTW raised concerns about access to the internet for uploading wound assessments in different settings. It was noted that connectivity in some hospitals in Wales can be poor and unreliable. Devices need to be able to store wound assessments 'off-line' for upload when possible. However, not all Wi-Fi networks are secure and patient data should not be transmitted over insecure connections. An additional challenge was identified in that existing health care data management systems used in community care, hospitals, by GPs and in nursing homes do not always communicate with each other. This may mean that the full capabilities of DWMS to integrate wound assessment and treatment plans into EHRs would not be realised.

Connectivity and access to DWMS may also be an issue for people living in rural parts of Wales. Experts noted that almost all patients treated for wounds have co-morbidities and around a third are over 65 years of age. They suggested that it is uncertain as to whether the systems are feasible for self-assessment in a population who potentially have problems with mobility or vision. There was evidence that patients were excluded from study participation due to inability to use a smartphone, or lack of access to a suitable smartphone. It is uncertain as to how equity in care quality for patients who lack digital access or digital literacy can be ensured, especially in situations where patients or carers may be imaging wounds themselves.

Experts also commented on the potential cost of DWMS. The need to acquire smartphones equipped with multiple high-quality cameras capable of producing 3D images, or an additional sensor, was suggested to be a barrier to adoption.

Most experts thought that DWMS would be appropriate for managing wounds in the community, despite potential issues with connectivity. However, in the acute setting, 30% to 50% of wounds treated were said to be in critical care areas. Wounds treated in critical care were reported as being larger than the maximum surface area for which reliability and validity data were available. The example of open abdominal wounds of 1000cm^2 with exposed bowel and blood vessels was given, with a query as to whether DWA could identify these. There was also a question as to whether DWA could differentiate between black necrotic plaques and black dry mummified tissue. It was suggested that it would not be appropriate to use one system to assess smaller wounds and a different one for larger, more complex wounds. For this reason, it was suggested that DWMS may not be suitable for use in the acute setting.

7. Patient, carer and family considerations

Papers capturing the experiences of people with wounds using digital technology to monitor their wound and treatment progression were identified as part of the main evidence search. In total, 10 papers relating the experiences of patients and carers were found (Ploderer et al. 2023, Sanger et al. 2014, Sreedharan et al. 2022, Lesher et al. 2023, Lo et al. 2023, Smith-Strøm et al. 2016, Søndergaard et al. 2023, Barakat-Johnson et al. 2022a, Boodoo et al. 2017, Ploderer et al. 2018). Of these, 6 were for patients with diabetic foot ulcers, 1 for children with burns, 2 for surgical site wounds and 1 for all wound types. Of the papers on diabetic foot ulcers, one was a scoping review. Digital tools identified included MyFootCare app, TOBI or the "TeleBurn," app and the Tissue Analytics digital application (TA app). Others were not named or were investigating 'telemedicine' with app technology in general. While some of these are not DWMS, and therefore excluded from the full clinical effectiveness review, the patient experiences and opinions reported within them can be fairly applied to other DWMS, such as taking photographs of wounds and using apps and devices. All apps were designed to be used by healthcare professionals, carers and patients themselves. Healthcare settings included care homes, community clinics and patient homes.

Methodologies across the studies included structured and semi-structured interviews and questionnaires. The studies were conducted in populations in the US, Singapore, Australia, Canada, Norway and Denmark.

The result of this literature search are as follows:

7.1 Wound care and self-management

Ploderer et al. (2018) note that 'the majority of diabetic foot ulcer care performed is by the patients themselves or their carers away from the clinic, as self-care'. This is also true for other wound types, such as surgical site infections (SSIs). Sanger et al. (2014) note that most SSIs occur post-discharge and wound tracking at home is an important to prevent re-admission. Similarly, burn care can be performed at home, reducing the need for hospitalisations or long trips to burn centres.

This can place a substantial burden on the part of the patient to ensure that their wounds are being well cared for and that treatment is being appropriately applied and progressing as expected. Patients can feel ill-equipped for the challenge of wound care at home (Sreedharan et al. 2022). Actions undertaken by patients can include regularly changing wound dressings, checking for changes and infection, wearing offloading devices to relieve pressure and protect the wound site (Ploderer et al. 2023) as well as making decisions and communicating with healthcare professionals. Lesher et al. (2023) describe how for burns, children and parents are often sent home with instructions on how to care for burns, however lack of experience and confidence can mean that parents can experience significant anxiety in changing burn dressings, which over time can led to poor adherence and delayed recovery. Additionally, patients can find it difficult to see, reach, and care for the wound themselves and healing changes can be hard to detect on a daily basis, which can be demoralising. Frequent visits to healthcare settings also impose a burden on patients (Lo et al. 2023). Having confidence that treatment is working is of fundamental importance to patients to provide reassurance and alleviate fears of new or worsening wounds and outcomes such as amputation (Smith-Strøm et al. 2016).

Importantly, patients who are involved in the care of their wound may be obliged to provide information to their healthcare providers and to recognise complications. The success of this will depend on the patient's understanding of their wound and their ability to communicate.

It is therefore necessary to help patients get accurate information on their wounds and the progress of treatment being made.

7.2 Common themes in patient experiences

7.2.1 Seeing progress in real time

Patients reported that using a digital device helped them to see the wound's progress for the better, where before this had been difficult to identify and could led them to feel discouraged about the self-care they were performing (Ploderer et al. 2023).

> *"[The ability to view past photos/history would be useful] because then you could see – oh, this is what this looked like 3 days ago and this is what it looks like now. This looks really different."*
>
> Patient quote from Sanger et al. (2014)

In their review, Søndergaard et al. (2023) noted that patients who reported wound assessments using pictures experienced a greater feeling of responsibility and awareness of changes, such as signs of infection or other changes, which encouraged them and enabled them to feel 'equal partners' in their care with their healthcare professional.

7.2.2 Informed decision making

Patients advised that the improved understanding of how their wound was healing and how their actions could affect it, such as being active when you have a foot ulcer, helped them to make better decisions related to their care. Having information available on wound care and educational information, such as diet, can be adopted to avoid further deterioration (Lo et al. 2023).

> *"It aided in the decision to stop work and improve."*
>
> Patient quote from Ploderer et al. (2023)
>
> *"More information. Because it takes a long time for the wound to heal. Everybody wants to know how fast can you heal the wound and what other things can help. Which other things… I, I look forward to."*
>
> Patient quote from Lo et al. (2023)

Sanger et al. (2014) noted how patients with SSIs felt an app could help them make important decisions regarding possible infections and answer their most prevalent question 'what should I do?'. Patients felt that it would improve their wound outcomes by being able to make their decisions quicker.

> *"But it would have been really helpful, especially the first time that it started getting infected, I could have sent them a picture or whatever and then if a day later - because it did, it got a lot worse. It was itching, it was bleeding and stuff - then I could have sent another picture and said it's a lot worse and they could have seen right then you need to come in now. Instead of waiting until it got really bad."*
>
> Patient quote from Sanger et al. (2014)

Lesher et al. (2023) noted how the provision of information in the form of FAQs (frequently asked questions) on their app "TeleBurn" were particularly helpful to parents and caregivers, of whom 73% found answers to their questions on burn care.

7.2.3 Improved communication and relationships with healthcare professionals

Patients found that the use of digital technologies can help them communicate with healthcare professionals more accurately and with more confidence, particularly when accessing several healthcare settings such as GP services and tissue viability services.

"But yeah, I think it's a good idea, because when I do go to my GP, I can show her the photos and how I've progressed, and now it's healed."

Patient quote from Ploderer et al. (2023)

"The digital communication between the outpatient clinic and the home care nurse, and image transfer gave [me a feeling of] security that, if there was some changes in the ulcer healing, the health professionals at the outpatient clinic would catch it."

Patient quote from Smith-Strøm et al. (2016)

Improved post-discharge information was also noted by Sanger et al. (2014) for people with SSIs. Patients talked about a post-discharge lack of information and felt that the app helped improve this deficit. They felt that the app helped them engage in and make decisions about their care. However, patients also noted that they did not want to be overwhelmed with information.

"Like if you forget how to clean and pack your wound or whatever, or if your wound looks like this, then [it's infected] - or if your wound looks like this, then [it's not infected]. That might be helpful… Mainly just in terms of if this happens, don't freak out. If this happens, do freak out."

Patient quote from Sanger et al. (2014)

Forms of communication were also discussed, with patients in Sanger et al. (2014) noting how for more serious concerns, a phone call was preferable, and that such options should be included in the app. The possibility that the app would help generate quicker responses to more serious concerns or wound problems was also discussed.

"The app should have] an option of how would you best like to be communicated with… Would you like it email, text message, phone call and they can select that, and it can go right in with the message. … Because [grandmother] would pick a phone call, [mother] and I would pick a text message."

Patient quote from Sanger et al. (2014)

It was noted in Søndergaard et al. (2023) that patients wish to be seen as 'a whole person', and not just a wound, by their healthcare professionals. Patients felt that using a mode of digital tool helped them be 'seen' by their doctors. The review also identified that communication was improved across healthcare settings and professionals, minimising the pressure on patients to 'keep track' of their wound history, appointments and 'who knows what' by remembering details of their treatment and wound progression.

However, patients in Barakat-Johnson et al. (2022a) noted how it was also important that clinicians engage with the tool in order for them to get the most out of it and provide continuity of care. Where clinicians were positive and engaged in the use of the tool, patients felt less alone and had increased confidence.

"feel like a doctor is right alongside me and they can look at it and analyse it and it's like having a doctor in another room. You don't feel isolated, and you feel that you're not on your own."

Patient quote from Barakat-Johnson et al. (2022a)

This sentiment was also seen in Boodoo et al. (2017) where patients expressed concern that the effectiveness of a tool would be dependent on clinician's responses, particularly the timeliness of responses. Some patients expressed that unless they knew that clinicians would respond in time, they would prefer not to use an app.

Smith-Strøm et al. (2016) also note how better continuity of care provides reassurance to patients. They note how patients prefer care from fewer nurses, because they felt that the nurses would be more familiar with their case and would be more up to date on the healing process and treatment procedure.

7.2.4 Engagement and usability

Generally, it was reported that patients could engage well with the digital tool in question. Digital tools were easy to use and inspired confidence in their users. Rates of use over longer periods of time varied from day to day and week to week. Engagement was influenced by several factors.

Facilitators to engagement included easy access, such as having them on mobile phones, familiarity with taking wound photos, training of care-givers to take photos, the potential that the use of the tool will negate the need for some appointments, more independence and being less of a burden on family and friends and potential environmental benefits from negating the need to attend unnecessary appointments (Søndergaard et al. 2023) as well as ease of use and usefulness of information available through the app (Lesher et al. 2023).

> *"Even sometimes, like, for, for this pandemic, if I have to stay home, I don't go, so that at least I can still check on my wound more regularly."*
>
> Patient quote from Lo et al. (2023)
>
> *"I'm not very tech savvy but it was actually pretty easy to navigate, dive straight into point, the communication on the app was very easy."*
>
> *"The answers that you can't find anywhere else, you can find in the app."*
>
> Patient quotes from Lesher et al. (2023)

Lo et al. (2023) also note that younger patients tend to prefer the convenience of an app, while older patients prefer an in-person consultation.

Barriers to engagement include health disruptions (ie hospitalisations) preventing or negating the use of the app, frustrations with healing progression, lack of confidence, accessibility issues (ie using glasses, bending into a position where the wound can be photographed, disabilities, visual impairments,) taking poor pictures and re-doing checks due to poor photographs, needing assistance to take photographs, developing the habit of taking wound pictures, reassurance and a preference for in-person consultations. For elder populations, Lo et al. (2023) noted that, in the case where the patient themselves is using the tool, step by step prompts on which buttons they should click to perform a certain function would be helpful.

Sanger et al. (2014) also note that patients have some concerns that apps should work equally well across devices (i.e., apple or android smartphones).

> *"My children, uh, my siblings, um, even the nurses, uh, those take care of me,… before the wound nurse we engage, before that, my daughter is the one who do the cleaning for me and dressing up the wound."*
>
> Patient quote from Lo et al. (2023)

Provision of a second language – other than English – is a finding from (Lo et al. 2023) that would be applicable to people in Wales, many of whom use English as a second language and where some people only speak Welsh.

Privacy and data security were also a patient concern according to Sanger et al. (2014), particularly as SSIs may occur in private areas that some may feel uncomfortable sending pictures of.

Lastly, Barakat-Johnson et al. (2022a) note how for patients, being able to conduct care in their own homes came with several advantages, including how being at home had a positive effect on wellbeing aiding in their recovery, as well as not needing to travel, the opportunity to adhere to their normal meal-time routines and the ability to have better sleep at home.

> *"It was easy for me to do that from home and for my wife to actually do the wound itself … and for us to send those photos … it was very convenient for us, otherwise we would have had to stay in (City). For us being at (rural), it made it so convenient for us and I had no issue with carrying it around in my pocket and I reckon it's the best thing that's happened."*
>
> Patient quote from Barakat-Johnson et al. (2022a)

7.2.5 Technological literacy

Ability to use smartphone technology will impact on a person's experience and confidence in digital tools for wound management.

Sanger et al. (2014) note how for some, too much technical information, wording, navigation and alerts may be difficult to follow and advise that for patients on pain medication, using an app might be difficult.

> *"But it would make a complex website or doing something complex, it would require you to remember several steps. I think [navigating a complex website under influence of drugs] would make it very difficult for a lot of people."*
>
> Patient quote from Sanger et al. (2014)

Other elements of the app design, such as lighting, text size, font, slow internet, sound quality and size of screen may have impacts on the patient's ability to use it well (Søndergaard et al. 2023). Considerations should also be made for patients with co-morbidities, such as using bright colours to help overcome vision issues caused by retinopathy (Boodoo et al. 2017).

Boodoo et al. (2017) noted how for older patients, experience with technologies is less prevalent as in other age groups, as they do not rely on technology in the same way for daily activities. This may mean that some older people may have a reluctance to use, or a dislike of, technology. While this study was conducted in Canada, it can be fairly applied to populations in Wales who may have similar backgrounds with technology.

> *"I actually don't do a lot with my phone other than I use it for emails and for phone calls. I am not a techy guy to use my iPhone all the time…It's a different generation I'm in…I have no need for it. That's the whole point of technology, it's gotta suit your needs. And it doesn't. I don't need it, so I don't use it."*
>
> Patient quote from Boodoo et al. (2017)

However, for patients in other age groups, technology is a way of life. They described technology as an important source of information and a means to satisfy daily needs, such as generating income, providing entertainment, and connecting with others via social media.

8. Conclusions

The aim of this rapid review was to examine the clinical and cost effectiveness of integrated digital wound care management systems compared with standard care. We identified nine cross-sectional studies examining reliability and/or concurrent validity of the automatic wound assessment component and seven feasibility or pilot studies and one describing use of DWMS in practice. There are uncertainties about reliability and validity of wound measurements conducted outside of controlled settings.

There is consistent evidence that, when wounds of between $3cm^2$ to $10cm^2$ are measured by trained staff, reliability for surface area is excellent. When compared with paper rulers or wound tracing there is evidence of good to excellent agreement between methods. There is evidence that the systems are poor at measuring depth.

Studies included qualitative reports that small wounds, very large wounds, wounds in skin folds or in contouring areas of the body were challenging for the systems to measure, and wound boundaries needed manual adjustment. In addition, three studies conducted in Singapore with mainly Chinese, Malay, or Indian patients commented that wounds on darker skin tones were more likely to need manual adjustment. We did not identify any validation studies where patients or carers took images in their own homes.

The nine studies that reported on aspects of clinical effectiveness were pilot or feasibility studies that aimed to test whether implementation of DWMS was practical. It appears that implementation of DWMS is feasible in a wide range of settings, particularly in community and nursing homes. There is evidence that patient satisfaction with using DWMS is good, but studies where patents uploaded their own images had high levels of exclusion due to inability to use or access the DWMS app. There is some evidence that wound documentation improves, and evidence that assessment time is faster when HCPs measure wounds using DWMS. Although wound healing outcomes were reported, demonstrating that it was feasible to collect the data, we were unable to determine whether wound healing improved after introduction of DWMS.

No health economic analyses were included in the health economic evidence review. HTW conducted a simple cost analysis based on the cost of the device, which was calculated using data from the manufacturer, and resource use based on a study included in the effectiveness section of the Evidence Appraisal Report. This was used to determine the number of assessments per week which would be required for no additional costs to be realised. Manufacturer data on current use of Minuteful for Wounds suggests that it is unlikely that use of the device would translate to cost savings.

From the patient experiences gathered, it appears the majority of participants perceived self-monitoring of wounds using digital tools valuable for their self-care, in particular to see the healing progress which encourages them to keep going with their wound-healing at home. Improvements in wound understanding also enables patients to make better decisions, leading to improved outcomes. Patients report that digital tools are mostly easy to use, engaging and helpful. Other benefits to patients include the ability to have questions answered, receive training and support, communicate with healthcare professionals and store information in one place. Being able to perform all these actions from home can lead to improvements in patient's wellbeing, including less time taken away for travelling to healthcare settings, improved sleep and other daily functions, and improved relationships with family, friends as well as clinicians and other healthcare professionals.

However, there are some groups for whom digital tools may not be an effective way to help manage their wounds at home. Some older people may have a preference for appointments over technology and a digital tool might not be something they could comfortably use. Digital tools may also present some challenges to people with visual disturbances, difficult to access wound site areas and other co-morbidities.

9. Contributors

This topic was proposed by Healthy.io

The HTW staff and contract researchers involved in writing this report were:

- A Evans – patient and public involvement author
- C England – clinical author
- D Jarrom – quality assurance of clinical section
- E Hasler – literature search and information management
- R Boyce – health economics author
- R Shepherd – project management
- S Hughes – quality assurance of health economics section

The HTW Assessment Group advised on methodology throughout the scoping and development of the report.

A range of clinical experts from the UK provided material and commented on a draft of this report. Their views were documented and have been actioned accordingly. All contributions from reviewers were considered by HTW's Assessment Group. However, reviewers had no role in authorship or editorial control, and the views expressed are those of Health Technology Wales.

Experts who contributed to this appraisal:

- Christina Harris, Cardiff and Vale University Health Board
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11. Evidence review methods

We searched for evidence that could be used to answer the review question: What is the clinical and cost effectiveness of integrated digital wound care management systems compared to standard care?

The criteria used to select evidence for the appraisal are outlined in Appendix 1. These criteria were developed following comments from the Health Technology Wales (HTW) Assessment Group and UK experts. All references identified by the literature searches were screened for eligibility by title and abstract. Where it was deemed that the title and abstract was potentially relevant, the full texts of articles were obtained and screened.

Studies were included if they evaluated DWMS as a complete system or evaluated one or two components of an identified system. For example, we included studies testing reliability and accuracy of imaging only, and included cohort and non-randomised comparative studies that were conducted without making full use of digital dashboards or end-to-end integration with EMR. We excluded studies that described the validation of AI-algorithms using training and testing datasets consisting of historic images of wounds, and studies that examined the accuracy of imaging systems by using plastic wounds, images of wounds from image datasets, or wounds in animals. We identified one potentially relevant systematic review of wound assessment, imaging and monitoring systems in diabetes related foot ulcer but this review included 17 studies, none of which were eligible for inclusion in our rapid review (Chan & Lo 2020). However, the review authors provided a list of wound assessment and monitoring systems available commercially which we used for cross-checking. A further two potentially relevant scoping reviews were identified but were excluded since one was a scoping review of development and validation of AI-algorithms (Dabas et al. 2023) and one was a very broad scoping review that did not identify the included studies (Shi et al. 2022).

The systematic search followed HTW's standard rapid review methodology. A search was undertaken of Medline, Embase, Cumulated Index to Nursing and Allied Health Literature (CINAHL), KSR Evidence, Cochrane Library, and the International Network of Agencies for Health Technology Assessment (INAHTA) HTA database. Additionally, searches were conducted of key websites and clinical trials registries. The searches were restricted to English language and publication years 2012 to 2023. The 2012 cut-off date was employed due to advancements in medical imaging technology that occurred at around this time. The searches were conducted in May 2023, with an update search of the key databases and citation tracking undertaken in October 2023. An additional search of named DWMS was undertaken in June 2023 and then updated in October 2023, and an additional search on surgical site infection with DWMS was undertaken in the key databases at the same time as the update search in October 2023. Appendix 2 gives details of the search strategy used for MEDLINE. Search strategies for other databases are available on request.

Appendix 3 summarises the selection of articles for inclusion in the review.

Appendix 1 – Inclusion and exclusion criteria for evidence included in the review

	Inclusion criteria	Exclusion criteria
Population	Patients receiving wound care in any setting (in-patient and community)	Malignant or suspected malignant dermatological lesions
Intervention	Integrated digital wound care management systems: 3D wound imaging, using software-assisted image processing to analyse images of wounds, integrated into patient electronic records.	Simple systems that only take 2D digital photographs for review by health care professionals
Comparison/ Comparators	Manual measurement of wounds with or without digital 2D photographs Real-time video conferencing	
Outcome measures	Time to wound healing Other wound healing outcomes (wound healing rate / complete closure / reduction in wound surface area / wound bed improvement) Accuracy of wound measurement Resolution of infection Number of amputations Adverse events Length of hospital stay Patient adherence to treatment Patient satisfaction and quality of life Resource use (e.g., number of consultations, time to assess wounds/staff time) Completion and accuracy of documentation	Reduction in microbial counts
Study design	We will prioritise the following study types, in the order listed: • Systematic reviews of randomised controlled trials. • Randomised controlled trials. • Non-randomised comparative trials. • Single-arm (no control group) trials that report any relevant outcome. We will only include evidence from "lower priority" sources where this is not reported by a "higher priority" source. This could be because higher priority evidence: • Does not cover all relevant populations. • Does not compare the technology of interest to all relevant comparators. • Does not cover all outcomes of interest.	

	Inclusion criteria	Exclusion criteria
	• Reports over short-term follow up periods, and longer follow up data is required to facilitate decision making. Where relevant and well-conducted systematic reviews exist, we will use these by: • Reporting or adapting their reported outcome measures where these are fully relevant to the scope of our review, and appropriate synthesis methods have been used. • Using these reviews as a source of potentially relevant studies where the review cannot be used as a source of outcome data. We will prioritise systematic reviews in terms of the sources of evidence they include, using the order described above.	
Search limits	Published since 2012	
Language limits	English language only	
Publication status	• We will include evidence from studies that are published in full. • We will only include evidence from conference abstracts if there are critical gaps in the fully published evidence. • We will include 'real-world' unpublished evidence where there are critical gaps in the fully published evidence. • We will include details of any ongoing trials that have a planned completion or reporting date within 24 months of the date searches are carried out. We will only include trials of a design that is likely to add to the existing evidence in terms of certainty; for example, if we report evidence from randomised controlled trials in the EAR, we will only report details of ongoing trials if they also use a randomised design.	
Subgroup analysis	Where the evidence allows, we will report outcomes separately according to: • Age • Sex • Severity and type of wounds	

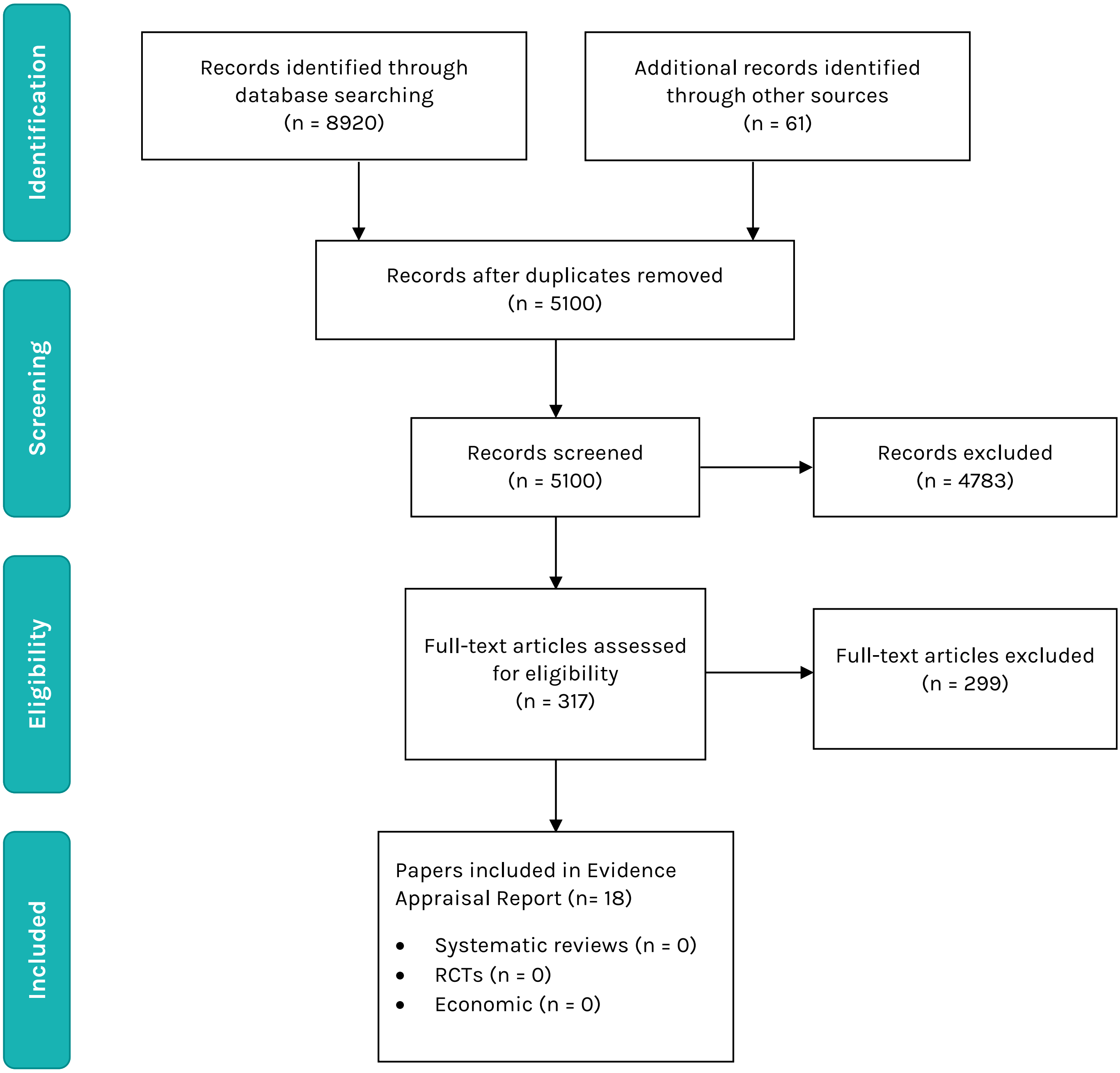
Appendix 2 – Medline strategy

Ovid MEDLINE(R) ALL 1946 to September 29, 2023		
Wounds		
1	"Wounds and Injuries"/	81554
2	(wound* adj2 injur*).kf.	20242
3	Wound Healing/	106610
4	exp Wound Infection/	52289
5	Diabetic Foot/	11497
6	Foot Ulcer/	2104
7	(diabet* adj6 (ulcer* or wound*)).tw,kf.	15308
8	DFU.tw,kf.	1904
9	Varicose Ulcer/	5368
10	Leg Ulcer/	8918
11	((venous or varicose or arterial or leg or legs or lower extremity) adj2 (ulcer* or wound*)).tw,kf.	12872
12	Skin Ulcer/	9367
13	Pressure Ulcer/	14026
14	((skin or pressure) adj2 (ulcer* or wound*)).tw,kf.	27681
15	(pressure adj2 sore*).tw,kf.	3375
16	(wound* adj3 (care or assess* or manag* or document* or measur* or monitor* or plan* or heal*)).tw,kf.	116190
17	((chronic* or non-heal* or nonheal* or tough or poorly heal* or painful or hard-to-heal or traumatic* or acute or complex) adj2 (ulcer* or wound*)).tw,kf.	28799
18	Burns/	48729
19	burn wound*.tw,kf.	6063
20	Leishmaniasis, Cutaneous/	7986
21	cutaneous leishmaniasis.tw,kf.	8517
22	or/1-21	417931
Digital/telemedicine/artificial intelligence		
23	Artificial Intelligence/	40464
24	(artificial* adj3 intelligen*).tw,kf.	40618
25	(AI adj3 (based or application* or intervention* or program* or therap*)).ti.	688
26	Telemedicine/	37931
27	Remote Consultation/	5764
28	Dimensional Measurement Accuracy/	647
29	(teledermatolog* or tele-dermatolog* or telemedicin* or tele-medicin* or telemedical* or tele-medical* or telehealth* or tele-health* or teleassess* or tele-assess* or teleconsult* or tele-consult*).tw,kf.	37998
30	(remote* adj3 (monitor* or consultation*)).tw,kf.	8659
31	Digital Technology/	756
32	Mobile Applications/	11737
33	*Cell Phone/	7435
34	exp Computers, Handheld/	13235
35	Medical Informatics Applications/	2551
36	Therapy, Computer-Assisted/	6975
37	(app or apps).tw,kf.	45133
38	(phone* or telephone* or smartphone* or cellphone*).ti.	27100
39	((phone* or telephone* or smartphone* or cellphone*) adj3 (based or application* or intervention* or program* or therap*)).ab,kf.	17482
40	(mobile health or mhealth or m-health or ehealth or e-health).ti.	8494
41	((mobile health or mhealth or m-health or ehealth or e-health) adj3 (based or application* or intervention* or program* or therap*)).ab,kf.	6067

42	((mobile* or online or web or internet or digital*) adj3 (based or application* or intervention* or device* or technolog*)).tw,kf.	117167
43	(digital* adj3 (health* or tool* or system or systems or measur* or planimetr*)).ti.	6215
44	"Imaging, Three-Dimensional"/	81607
45	"Image Processing, Computer-Assisted"/	140570
46	Image Interpretation, Computer-Assisted/	47850
47	computer-assisted.hw.	334024
48	or/44-47	385191
49	Software/	125914
50	48 and 49	23265
51	*"Imaging, Three-Dimensional"/	39016
52	*"Image Processing, Computer-Assisted"/	52914
53	"Image Processing, Computer-Assisted"/is [Instrumentation]	5425
54	*Image Interpretation, Computer-Assisted/	32367
55	Image Interpretation, Computer-Assisted/is [Instrumentation]	1983
56	*Photography/	13082
57	*"Photogrammetry"/	1352
58	((three-dimen* or 3-dimen* or 3D or 3-D) adj3 (imag* or camera* or photograph* or measur* or assess*)).tw,kf.	60891
59	(digital adj (imag* or camera* or photograph*)).ti.	3828
60	*"Forms and Records Control"/	2558
61	*Documentation/st	2272
62	*Electronic Health Records/st	1532
63	(store* adj3 forward*).tw,kf.	711
64	or/23-43,50-63	491937
Set combination		
65	22 and 64	3528
66	limit 65 to (english language and yr="2012 -Current")	2200
67	Animals/ not Humans/	5125264
68	66 not 67	2076
69	surgical site infection*.mp.	16413
70	(wound adj3 (imag* or evaluat*)).tw,kf.	3827
71	69 or 70	20168
72	64 and 71	382
73	72 not 66	143
74	limit 73 to (english language and yr="2012 -Current")	77
75	74 not 67	75

Ovid MEDLINE(R) ALL 1946 to September 29, 2023		
Named DWMS		
1	minuteful*.af. and (wound* or ulcer*).ti.	1
2	Tissue* Analytics*.af. and (wound* or ulcer*).ti.	5
3	((eKare or e-Kare) and (wound* or ulcer*)).af.	3
4	(wound* adj3 viewer).af.	1
5	WoundAide*.af.	2
6	Cares4Wound*.af.	1
7	swift medical.af. and (wound* or ulcer*).ti.	10
8	(swift adj4 app).af.	6
9	"Skin and Wound application".af.	2
10	WoundVue*.af.	2
11	or/1-10	31

Appendix 3 – Flow diagram outlining selection of relevant evidence sources



Appendix 4 – Full sources of evidence and outcome data

Table A1 – Reliability and concurrent validity: design and characteristics

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Comments
Aarts et al. (2023)	• Prospective study • Study period: February 2021 to May 2021 • Setting: Dermatology clinic • Location: Netherlands	• Raters: 3 • Patients/wounds: 20/52 • Images: 52 • Images excluded: 0 • Type of wounds: surgical HS wounds • Females: 15; Males: 5 • Median (IQR) age: 37.5 (IQR 28.5–50.75) yrs • Ethnicity NR	• Tablet plus sensor 3D DWA by a physician, nurse practitioner and medical student. Each HCP conducted one measurement using the device. • Product and manufacturer: inSight, eKare • Reference: 1) using a ruler to measure length and width and calculate surface area from ruler measurements (length x width x 0.73) or 2) Manual planimetry (Opsite Flexigrid) by one of physician, nurse practitioner or medical student on the same day.	• Test-retest reliability • Inter-rater reliability • Concurrent validity	• Large wounds excluded due to the size of the tracing grid (15 x 20cm). • Unclear if assessments were conducted independently. • Unclear if patients were repositioned between tests for reliability.
Anghel et al. (2016)	• Prospective study • Setting: Wound clinic • Study period: September 2015 • Location: USA	• Raters: 2 • Patients/wounds: 31/45 • Images: 135 • Images excluded: 0 • Type of wound: NR • Sex: NR • Age: NR • Ethnicity: NR	• Tablet (iPad) plus sensor 3D DWA conducted by trained raters, profession NR. Each wound was imaged by the device 3 times (averaged for concurrent validity). • Product and manufacturer: inSight, eKare. • Reference standard conducted by rater 1: 1) 2D digital planimetry (ImageJ software, National Institute for Health) 2) using a ruler to measure length and width and calculate surface area (length x width), a cotton swab for depth and with saline solution for volume.	• Test-retest reliability • Interrater reliability • Concurrent validity	• Wounds excluded if they were circumferential or not within easily visualised areas. • Raters for inter-rater reliability were instructed not to reveal results to each other. • Rater 1 also conducted references measures. • Unclear if patients were repositioned between tests. • All images were taken at 40 to 50 cm distance, at a perpendicular angle. • This version of Insight is an early version that automatically calculates wound dimensions but not by using AI.

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Comments
Chan et al. (2022)	• Prospective study • Setting: Outpatient/inpatient clinics • Study period: June 2020 to January 2021 • Location: Singapore	• Raters: 2 • Patients/wounds: 28/75 • Images: 547 • Images excluded: 128 • Type of wounds: diabetes related foot ulcer • Females 4; Males 24 • Median (IQR) age (yrs): 60 (52.5–66) • Ethnicity: Chinese 17; Malay 2; Indian 9	• Smartphone-based 3D DWA (iPhone 8 Plus, iPhone 11 Pro, iPhone XS all running iOS13) conducted by research co-ordinator. Each wound was imaged three times on each device. • Product and manufacturer: Cares4Wounds (Version 1, build 1), Tetsuyu • Reference standard conducted by wound nurse: manual planimetry	• Test-retest reliability for each phone • Intra-rater reliability between the three phones • Concurrent validity	• Unclear if wound nurse conducted assessments independently. • Patients and the rater were moved between each image. • Measurements were conducted in a room with adequate lighting. • Images were captured at approximately 20cm. • All patients were treated with a standardised wound management pathway with standardised follow up. Wound measurements occurred at standard clinic visits.
Fong et al. (2023)	• Prospective study • Setting: Outpatient wound clinic • Study period: June 2020 to March 2021 • Location: Singapore	• Raters: 3 (one using DWA; two conducting standard measures) • Patients/wounds: 82/358 • Images: 2334 • Images excluded: 536 • Type of wounds: venous leg ulcer • Females: 40; Males: 42 • Mean (SD) age (yrs): 65.8 (11.7) • Ethnicity: Chinese 56; Malay 10; Indian 9; Others 7	• Smartphone-based 3D DWA (iPhone 11 running iOS13, XiaoMi Mi Max2 running Android 7.0) conducted by research co-ordinator. Each wound was imaged three times on each device. • Product and manufacturer: Tissue Analytics, Net Health • Reference standard conducted by one of two wound nurses: manual planimetry	• Test-retest reliability for each device • Inter-rater between devices on iOS and Android • Concurrent validity	• Wound nurse conducted reference assessments independently. • Patients and the rater were moved between each image. • Assessments were conducted in a room with adequate lighting from the ceiling. • Images were captured at approximately 40cm.
Jun et al. (2019)	• Retrospective study • Setting: Medical records	• Raters: NR • Patients/wounds: NR/26 • Images: 26 • Images excluded: 206	• Tablet (iPad min) plus sensor 3D DWA conducted by hospital staff. Each wound was imaged once.	• Concurrent validity	• Images were excluded if they had non-valid or poor-quality measurements or had missing data.

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Comments
	• Study period: October 2017 to December 2018 • Location: South Korea	• Type of wound: Cleaned and, if necessary, surgically debrided pressure ulcers • Sex: NR • Age: NR • Ethnicity: NR	• Product and manufacturer: inSight, eKare • Reference standard conducted by hospital staff: Width, length and surface area measured using 2D digital planimetry; depth measured using sterile rulers; volume measured by saline filling.		• Unclear if assessments were conducted independently. • Unclear if patients were moved between images.
Swerdlow et al. (2023)	• Prospective study • Setting: Wound clinic • Study period: 40-day period, dates NR • Location: USA	• Raters: 2 • Patients/wounds: 30/42 • Images: 210 • Images excluded: NR • Type of wounds: diabetes related foot ulcer, venous ulcers, pressure injury, burn, autoimmune lesions, and iatrogenic wounds • Sex NR • Age NR • Ethnicity NR	• Tablet (iPad mini) plus sensor (1 x image) and smartphone-based 3D DWA (iPhone 12 x 1 image, and iPhone 13 x3 images) conducted by medical students with minimal prior experience of the device. • Product and manufacturer: inSight, eKare • Reference standard: none	• Test-retest reliability • Interrater reliability for raters • Interrater reliability for devices	• Wounds with difficult topography (e.g., circumferential wounds) were excluded. • Unclear if assessments were conducted independently. • Unlikely that patients were moved between images (each wound was imaged 3x over a 2 min period). • User must use the touchscreen to circle the wound and swipe the wound to activate the measurement algorithm.
Toygar et al. (2020)	• Prospective study • Setting: Diabetic foot clinic • Study period: NR • Location: Turkey	• Raters: 1 • Patients/wounds: 20/20 • Images: 20 • Images excluded: 7 • Type of wounds: cleaned, debrided diabetes related foot ulcer • Females: 7; Males: 13 • Mean (SD) age (yrs): 58.6 (6.0) • Ethnicity: NR	• Tablet (iPad) plus sensor 3D DWA conducted by a researcher. • Product and manufacturer: InSight eKare • Reference standard conducted by the same researcher: 1) Manual planimetry 2) 2D digital planimetry (ImageJ software, National Institute of Health)	• Concurrent validity	• Wounds with gangrene (Wagner stages 4 and 5) were excluded due to inability to trace wound edges or inability to photograph. • Assessments were conducted by a single rater sequentially. • Unclear if patients were moved between images.

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Comments
Wang et al. (2017)	• Prospective study • Setting: Wound clinic • Study period: NR • Location: Canada	• Raters: 3/2 • Patients/wounds 87/87 • Images: 90 • Images excluded: NR • Type of wound: cleaned, debrided wounds related to diabetes, venous insufficiency, and pressure ulcers • Sex: NR • Age: NR • Ethnicity: NR	• Smartphone-based DWA (iPhone 6 running iOS8.4) conducted by a physician, nurse, and medical student (wounds=45) • Product and manufacturer: Swift Wound, Swift Medical • Reference standard conducted by two nurses: Ruler measurements (wounds=42)	• Inter-rater reliability calculated for each method independently.	• Wounds larger than 17cm in either dimension were excluded. • Assessments were conducted independently. • Images were captured from 20 to 30cm, perpendicular to wound. • This version of Swift Wound is an early version that automatically calculates wound dimensions but not by using AI. User loosely traces the wound on the touchscreen and can choose to accept the automatic identification of wound boundaries or to adjust them prior to calculation.
Zoppo et al. (2020))	• Prospective study • Setting: Surgical ward • Study period: NR (ethical approval obtained October 2017) • Location: Italy	• Raters: 1 team of 3 HCPs (+3 person data team) • Patients/Wounds; 150/150 • Images: 150 • Images excluded: NR • Type of wound: Lower limb ulcers, diabetes related foot ulcer, pressure ulcers • Sex: NR • Age: NR • Ethnicity: NR	• Proprietorial device-based 3D DWA conducted by an HCP assessment team (2 physicians and one nurse). HCPs imaged the wound once and the data team ran the assessment algorithm separately. • Product and manufacturer: Wound Viewer, Omnidermal • Reference standards conducted by the HCP assessment team: 1) “Visual assessment” 2) 2D digital planimetry (Visitrak, Smith+Nephew) 3) use of a scaled probe	• Agreement for WBS (Wound Viewer and visual assessment) • Surface area (Wound Viewer and Visitrak) • Depth (Wound Viewer and probe)	• Wounds were excluded if there was acute skin damage or areas of undermining. • Wounds <2cm^2 and >100cm^2 were excluded. • Assessments were conducted independently. • Unclear if patients were moved between images. • A technician was available for troubleshooting any technical issues.

Abbreviations: 2D=2 dimensional; 3D=3 dimensional; DWA=digital wound assessment; HCP=health care professional; NR=not reported; yrs=years

Table A2 – Effectiveness studies: design and characteristics

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Follow up	Comments
Au et al. (2019b)	• Prospective cohort with historic comparator • Study period: C: Q2 2015 to Q4 2016; I: Q1 2017 to Q1 2018 • Duration of participation: NR • Setting: Inpatient nursing facility • Location: USA	• Nursing home residents • N:NR • N wounds: NR • Wound type: Pressure ulcers • Severity of illness: NR • Sex: NR • Age: NR • Ethnicity: NR	• **Intervention:** Smartphone-based 3D DWMS • Wounds were assessed and monitored using DWMS by the MDT. • Product and manufacturer: Swift Skin and Wounds (Swift Medical) • **Comparator:** Conventional ruler-based measurement and drawing method. Data entered manually. Note: All patients, with and without wounds were given weekly skin checks and managed using set procedures. Patients with complex wounds were transferred to a dedicated wound care clinic for further treatment.	• Median percentage of short-term and long-term residents with pressure ulcers • Qualitative reporting of the effect of Swift Skin and Wound on documentation, wound management, and data entry time.	• 12 months	• Prevalence of pressure ulcers is a quality metric in the nursing facility. • This was a quality audit to examine the consequence of a change in wound management, specifically adoption of a DWMS, but a skin integrity coordinator also joined at the same time as the app was adopted and other improvements such as changes to the types of beds used were implemented. • Descriptive statistics only.
Barakat-Johnson et al. (2022a)	• Non-randomised comparative study • Study period: December 2019 to October 2020 • Duration of participation: C 4m; I 5m • Setting: Ward-based 86%; community 14% • Location: Australia	• Patients with wounds aged >18 yrs in participating sites. • N: 290 (I=124; C=166) • N wounds: 427 (I=184; C=243) • Withdrawals: 0 • Wound type: Multiple • Severity of illness: NR • Sex: I: 65 (52.4%) male, 59 (47.6%) female; C: 85	• **Intervention:** Smartphone-based 3D DWMS Nurses and doctors used the app to take photos of the wound and document assessment and management; patients who were monitored at home used the app to take photos and upload for review. • Product and manufacturer: Tissue Analytics, Net Health • **Comparator:** Use of a wound documentation system, with	• I only: Change in surface area • Completion and accuracy of documentation	• Point of discharge (inpatients) • 3 months after enrolment (community)	• Patient data were collected via medical records and were compared with data collected prior to implementation. • The DWMS does integrate with e-Medical records, but this study examined a stand-alone version only. • Descriptive statistics only for wound outcomes

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Follow up	Comments
		(51.2%) male, 81 (48.8%) female • Age: I=69.87 (18.66); C=72.01 (18.46) • Ethnicity: NR Patients with diagnosed non-healing wounds; burns/scalds and superficial wounds were excluded.	text description of wounds and 2D wound images stored on a separate computer drive			• Health professionals surveyed and interviewed. Data not formally extracted for this EAR, but positive around usefulness and usability. • Study was paused in March 2020 for 3 weeks due to Covid-19 pandemic.
Barakat-Johnson et al. (2022b)	• Prospective cohort • Study period: Recruitment between 17/12/2020 to 28/05/2021 • Duration of participation: Until wound healed or end of data collection on 6/08/2021 • Setting: Nine different centres in metropolitan and rural health services in one state • Wound specialists (n=19) recruited to enrol and monitor patients from their caseloads • Location: Australia	• Patients receiving wound care from a participating HCP • N: 69 • N wounds: 65 • Withdrawals: 18 • Analysed: 51 (61 wounds) • Wound type: Multiple • Severity of illness: NR • Female 24; Male 27 • Mean (SD) age: 61.9 (13.4) yrs • Ethnicity: NR Patients with diagnosed non-healing wounds; burns/scalds and superficial wounds were excluded. Total screened: 405 Ineligible: 28 (7%) Unable to access app: 168 (41%)	• **Intervention:** Smartphone-based 3D DWMS • Patients (n=51) took wound photos and uploaded them for review by treating HCPs and wound specialists. App did not replace appointments with participating HCPs but provided additional support between appointments. • Product and manufacturer: Tissue Analytics, Net Health • **Comparator:** Care prior to recruitment to the study (same participants) consisting of triage by community nurse and, for non-urgent cases, an average 2-week wait between appointments with treating HCPs. Patients unable to contact wound specialist team directly.	• Patient satisfaction • I only: Complete closure in ≤12wks • I only: Time to complete closure • I only: Wound healing rate • I only: Contact with HCPs	• 7 months	• Unclear how the wound specialists were selected. • Study specific surveys used for patient satisfaction. • Descriptive statistics for patient satisfaction • Contact was captured by the app and included any examination, consultation, treatment, or other service provided in a non-hospital setting, excluding telephone calls. • Average HCP contact per participant calculated through linear regression.

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Follow up	Comments
		Image capture was too difficult due to location of wound: 68 (17%) Other: 102 (25%)				
Healthy.io. (2023) Unpublished data	• Retrospective cohort • Study period: From adoption to August 2023 • Analysis period: 0 to 8 months after adoption at each site • Setting: Three community healthcare services • Location: England and Wales	• Patients with new wounds in participating sites • N: 11,668 • N wounds: 28,383 • Withdrawals: NR • Wounds analysed: 10, 879 • Wound type: Multiple, includes vascular wounds, diabetes related wounds, and non-chronic wounds • Severity of illness: NR • Female 54%; Male 46% • Age (yrs) <60: 1662 (14%); 61 to 70: 1458 (12%); 71 to 80: 2620; >80: 5928 (51%)	• **Intervention**: Smartphone and tablet-based 3D DWMS • Wound images and assessments taken by HCPs and uploaded to the digital dashboard for review and to facilitate caseload management. • Product and manufacturer: Minuteful for Wounds, Healthy io. • **Comparator:** Baseline was taken as the first three months after implementation. No comparison with usual care.	• Complete closure in ≤12wks • Resource use	• 8 months	• Unpublished real-world evidence from pilot rollouts of the DWMS in three sites in the UK. • Analysis is based on a subset of the data, using the first 8 months of adoption at each site. • Comparisons between binomial distributions were made based on the Agresti-Coull method. • Very limited information about patients was available. • Usual care at each site is not described. • No adjustment for covariates
Keegan et al. (2023)	• Prospective cohort • Study period: July 1st to November 30th 2022 • Duration of participation: 8 weeks • Setting: Patient home • Location: USA	• Patients with an active diabetes related foot ulcer • N: 25 • N wounds: 179 scans • Withdrawals: 0 • Wound type: Diabetes related foot ulcer • Severity of illness: Independent 18 (72%); Partially dependent 7 (28%)	• **Intervention:** Smartphone-based 3D DWMS • Patient (n=10) or carer (n=15) were asked to upload weekly wound scans for review by treating HCPs • Product and manufacturer: Minuteful for Wounds, Healthy. Io Ltd • **Comparator:** None	• Adherence to treatment • Resource use • Patient satisfaction • Wound healing	• 8 weeks	• An 8-week follow up may not be long enough to obtain outcome data. • Exclusion criteria may be restrictive in practice. • Change in wound area over the course of the study was compared using paired t-tests. • No adjustment for covariates.

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Follow up	Comments
		• Female: 10; Male: 15 • Mean (SD) age: 65.5 (13.7) yrs • Ethnicity: Non-Hispanic Black 13 (52%); Non-Hispanic White 12 (48%) Patients were excluded if the wound was too large to be imaged in a single scan or in a location that was inaccessible to patient/carer or they were unable to use the smartphone app.	• 7 (28%) patients who did not own a compatible smartphone were provided with one for the duration of the study.			• Study specific surveys were used to collect patient satisfaction data. • Data on the quality of scans was also collected: 145/179 were valid on the first attempt. • This was a feasibility study so major changes in wound management were not solely based on wound images, but authors report that images were used in conjunction with outpatients' appointments. 36% of patients were advised that their wound management plan was to change based on the weekly review of their wound scan.
Lim et al. (2022)	• Non-randomised comparative study • Study period: 11/2020 to 1/2021 • Duration of participation: 2m • Setting: Nursing homes (one intervention / one standard care)	• Nursing home residents with chronic wounds • N: 9 (I=5; C=2) • N wounds: NR • Withdrawals: 2 • Wound type: NR • Severity of illness: NR • Sex: NR • Age: NR	• **Intervention:** Smartphone-based 3D DWMS • Nursing home staff assessed wounds using the app. A wound specialist provided remote guidance on care and in-person assessment every two weeks. In addition to measurement the app used an algorithm to advise on management, including use of generic dressings, wound	• Complete closure • Change in surface area • Wound bed improvement • Resource use	• 8 weeks	• An 8-week follow up may not be long enough to obtain outcome data. • Blinding of the wound specialist was not possible. • The study was conducted in two nursing homes in Singapore and likely to not be generalisable to Wales.

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Follow up	Comments
	• Location: Singapore	• Ethnicity: NR Patients <18yrs, medically unstable, with a life expectancy <2months, or had complex wounds requiring specialist care in an acute hospital.	cleaning solutions, additional skin products and use of debridement. • Product and manufacturer: Cares4Wounds, Tetsuyu Homecare. • **Comparator**: Wounds were managed conventionally by nursing home staff in a separate nursing home, with weekly in-person assessment by the wound specialist.			• Descriptive statistics only. • The study was conducted during the 2020 Covid pandemic and there were strict quarantine measures that limited recruitment and may mean the study is not generalisable. • System usability scale scores also collected. Average score was low due to technical connectivity issues; the app being unable to distinguish the wound on darker skin tones and staff being unfamiliar with advised generic dressings.
Mohammed et al. (2022)	• Time and motion study • Study period: 24/01/2022 to 7/02/2022 • Duration of participation: 2wks • Setting: Outpatient wound clinic • HCPs (n=5) recruited measure wounds using both methods • Location: USA	• Patients requiring wound assessment • N: 91 • N wounds: 115 • Wound type: Multiple • Withdrawals: 0 • Severity of illness: NR • Sex: female 49 (53.8%); male; 42 (46.2%) • Age (mean): 62.8yrs • Ethnicity: NR	• **Intervention:** Tablet-based (iPad) 3D DWMS • Nurses measured wounds using 3D DWMS and recorded time taken to complete assessment. Recording started when the iPad was touched, and a fiducial marker was placed next to the wound. Recording finished when a satisfactory image was captured, and the iPad put down. Time taken to upload confirm measurements and transfer	• Time to assess wounds	NA	• The study only considered time to assess wounds by 5 nurses. • No wound measurement data was retained. • Fourteen wounds were assessed by both methods by each nurse independently to ensure consistency (data available in the paper)

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Follow up	Comments
			images to EAR was also recorded. • Product and manufacturer: Swift Skin and Wounds (Swift Medical) • **Comparator:** Nurses measured wounds using paper-ruler method and 2D images of wounds taken with a digital camera and transferred to a computer and recorded time taken to complete assessment			
Oliver et al. (2023)	• Service evaluation • Study period: NR • Duration of participation: NR • Setting: Community care • Location: UK	• N: 127 • N wounds: NR • Withdrawals: NR • Wound type: foot-related • Severity of illness: NR • Sex: NR • Age: NR • Ethnicity: NR	• **Intervention:** Smartphone-based 3D DWMS • Patients identified as having potentially deteriorating wounds who were reviewed via the DWMS dashboard by a senior team of wound experts. • Product and manufacturer: Minuteful for Wounds, Healthy.io Ltd • **Comparator:** Patients identified as having potentially deteriorating wounds who were not reviewed via the DWMS dashboard by a senior team of wound experts.	• Proportion of improved wound	• NR	• Authors report that the sample of reviewed patients in podiatry was small compared to the overall number of non-podiatry patients whose wounds were deteriorating. • Authors report that the senior review process was not standardised. • Unclear as to the timescales involved. • Evaluation was not long enough to assess healing rates.
Wynn & Scholes (2022)	• Prospective cohort with historic comparator • Study period: 7-month study, dates NR	• N: "Over 300" • N wounds: "Over 800" • Withdrawals: NR • Wound type: NR • Severity of illness: NR • Sex: NR	• **Intervention:** Tablet-based 3D DWMS • Staff in an acute medical unit were given access to the app and documented wound care	• Completion and accuracy of documentation	• 7 months	• Authors note that this was a brief report of implementation in a single hospital acute medical unit and may not be generalisable.

Study reference	Methods, setting	Participants	Intervention(s)	Outcomes	Follow up	Comments
	• Duration of participation: NR • Setting: Acute medical unit inpatients • Location: England	• Age: NR • Ethnicity: NR	via the app for remote review by tissue viability nurses. • Product and manufacturer: Minuteful for Wounds, Healthy. io Ltd • **Comparator:** Standard care in the 3 months prior to implementation of the DWMS, involving requesting wound photographs be obtained and uploaded to a server for review by tissue viability nurses. This could take several days.			• Authors qualitatively report that there were challenges during the implementation period due to software compatibility issues and poor initial engagement by staff. Engagement improved when an 'app' champion was identified to be responsible for encouraging use. • Descriptive statistics only

Abbreviations: 2D=two dimensional; 3D=three dimensional; m=months; NA=not applicable; wks=weeks; yrs=years

Table A3 - Reliability of digital wound image measurements

Outcome	DWMS technology	Evidence source(s)	Study design (wounds/images) Types of wounds	Wound dimensions[1]	Results (ICC (95%CI) unless otherwise indicated) [Interpretation]	Comments on study reliability
Test-retest reliability for surface area, length, and width	Insight, eKare	Aarts et al. (2023)	Prospective study (52/52) Surgical HS wounds	Median (IQR) surface area: 10.1 (5.8–23.3) cm^2 Mean (range) surface area: 18.7 (2.5 to 95.8) cm^2	**Surface area:** 0.998 (0.996, 0.999) SEm: 0.95cm^2 MDC: 2.6cm^2 **[Excellent test-retest reliability]** Mean difference (LoA) -0.35 (-2.9, 2.2) cm^2 Systematic bias: -0.026cm^2	• No pre-defined acceptable LoA
		Swerdlow et al. (2023)	Prospective study (42/168) Multiple wound types	Mean (SD) surface area: 4.3 (5.4) cm^2 Range 0.2 to 23 cm^2	**Surface area:** 0.997 (95%CI NR) **[Excellent test-retest reliability]** Difference between mean surface area between tests (ANOVA), p>0.05 **[No evidence for a difference in means between tests]**	• iPhone 13 only
		Anghel et al. (2016)	Prospective study (45/NR) Wound type NR	NR	**Surface area:** 0.998 (0.997, 0.999) **Length:** 0.997 (0.995, 0.998) **Width:** 0.995 (0.991, 0.997) **[Excellent test-retest reliability]**	• Authors note that the device did not function well in low light conditions.
	Tissue Analytics, Net Health	Fong et al. (2023)	Prospective cohort study (358/2334) Venous ulcers	Median (IQR) surface area: 3.55 (1.40, 9.23) cm^2	**Surface area** iOS: 0.974 (0.969, 0.978) Android: 0.981 (0.977, 0.984) **Length** iOS: 0.985 (0.982, 0.987) Android: 0.984 (0.981, 0.987) **Width** iOS: 0.967 (95% CI: 0.960, 0.972) Android: 0.977 (95% CI: 0.973, 0.981) **[Excellent test-retest reliability on both devices]**	• 356 images excluded for reasons unrelated to image quality. • Manual adjustments had to be made to the automatic wound boundaries

Outcome	DWMS technology	Evidence source(s)	Study design (wounds/images) Types of wounds	Wound dimensions[1]	Results (ICC (95%CI) unless otherwise indicated) [Interpretation]	Comments on study reliability
						when there was poor colour contrast with skin tone, wounds <1cm or were in areas with large amounts of skin contouring.
	Cares4Wounds, Tetsuyu	Chan et al. (2022)	Prospective study (75/547) Diabetes related foot ulcers	Median (IQR) surface area: 3.10 (0.60, 14.84) cm^2	**Surface area** iPhone 8 Plus: 0.984 (0.974, 0.990) iPhone 11 Pro: 0.994 (0.991, 0.996) iPhoneXS: 0.994 (0.991, 0.996) **Length** iPhone 8 Plus: 0.956 (0.931, 0.973) iPhone 11 Pro: 0.993 (0.989, 0.995) iPhoneXS: 0.984 (0.976, 0.990) **Width** iPhone 8 Plus: 0.946 (0.917, 0.967) iPhone 11 Pro: 0.933 (0.901, 0.957) iPhoneXS: 0.963 (0.944, 0.977) **[Excellent test-retest reliability on all devices]**	• 128 images excluded due to poor imaging technique. • Manual adjustments had to be made to the automatic wound boundaries when there was poor colour contrast with skin tone, wounds <1cm or were in areas with large amounts of skin contouring.

Outcome	DWMS technology	Evidence source(s)	Study design (wounds/images) Types of wounds	Wound dimensions[1]	Results (ICC (95%CI) unless otherwise indicated) [Interpretation]	Comments on study reliability
Test-retest reliability for depth and volume	Insight, eKare	Anghel et al. (2016)	Prospective study (45/NR) Wound type NR	NR	Depth: 0.360 (0.079, 0.588) **[Poor test-retest reliability for depth]** Volume: 0.888 (0.806, 0.937) **[Good test-retest reliability for volume]**	• Authors comment that one rater lacked consistency with camera angles and hypothesised that this was one reason for poor test-retest reliability.
Inter-rater reliability for surface area	Insight, eKare	Aarts et al. (2023)	Prospective study (52/52) Surgical HS wounds	Median (IQR) surface area: 10.1 (5.8–23.3) cm² Mean (range) surface area: 18.7 (2.5 to 95.8) cm²	**Surface area:** 0.997 (0.995–0.998) SEm: 1.11cm² MDC: 3.1cm² **[Excellent agreement between raters]** Mean difference (LoA) -0.12 (-3.1, 2.9) cm² Systematic bias: -0.027cm²	• No pre-defined acceptable LoA
		Swerdlow et al. (2023)	Prospective study (42/168) Multiple wound types	Mean (SD) surface area: 4.3 (5.4) cm² Range 0.2 to 23 cm²	Between raters **Surface area:** 0.998 (95% CI NR) **[Excellent agreement between raters]** Difference between mean surface area between raters (ANOVA), p>0.05 **[No evidence for a difference in mean between raters]** Between devices (iOS13 v iOS12; iOS13 vs iPad/Sensor; iOS12 vs iPad/Sensor) **Surface area:** r = 0.999 for all comparisons. **[Excellent correlation between devices]**	• Authors suggest that use of a smartphone is more convenient than an iPad mini with additional sensor.

Outcome	DWMS technology	Evidence source(s)	Study design (wounds/images) Types of wounds	Wound dimensions[1]	Results (ICC (95%CI) unless otherwise indicated) [Interpretation]	Comments on study reliability
					Difference between mean surface area between devices (t-test), iOS13 vs iOS12, p=0.222 iOS12 vs iPad/Sensor, p=0.781 **[No evidence for a difference in mean between devices]** iOS13 vs iPad/Sensor Difference in means = 1.39%; standardised mean difference (Cohen's d) = 0.01, p=0.05 **[Effect size is very small and not clinically meaningful]**	
		Anghel et al. (2016)	Prospective study (45/NR) Wound type NR	NR	**Surface area:** 0.999 (0.998, 0.999) **Length:** 0.997 (0.995, 0.998) **Width:** 0.995 (0.991, 0.997) **[Excellent agreement between raters]**	• Authors note that the device did not function well in low light conditions.
	Tissue Analytics, Net Health	Fong et al. (2023)	Prospective study (358/2334) Venous leg ulcers	3.55 (1.40-9.23) cm^2	Between apps running on iOS or Android **Surface area:** 0.987 (0.984, 0.990) **Length:** 0.989 (0.987, 0.991) **Width:** 0.988 (0.984, 0.990) **[Excellent agreement between devices]**	• The same rater used the DWA app on an iPhone or Android smartphone.
	Cares4Wounds, Tetsuyu	Chen et al. (2022)	Prospective study (75/547) Diabetes related foot ulcers	3.10 (0.60–14.84) cm^2	**Surface area:** 0.965 (0.949, 0.977) **Length:** 0.947 (0.923, 0.964) **Width:** 0.923 (0.890, 0.948) **[Excellent agreement between devices]**	• 128 images excluded due to poor imaging technique. • Manual adjustments had to be made to the automatic wound

Outcome	DWMS technology	Evidence source(s)	Study design (wounds/images) Types of wounds	Wound dimensions[1]	Results (ICC (95%CI) unless otherwise indicated) [Interpretation]	Comments on study reliability
						boundaries when there was poor colour contrast with skin tone, wounds <1cm or were in areas with large amounts of skin contouring.
	Swift Wound, Swift Medical	Wang et al. (2017)	Prospective study (87/219) Wounds related to diabetes, venous insufficiency, and pressure ulcers.	Range 0.2 cm^2 to 60 cm^2	**Surface area** (DWA only): 1.00 (0.99, 1.00) **Length** DWA 0.98 (0.98, 0.99) Ruler 0.92 (0.86, 0.96) **Width** DWA 0.97 (0.95, 0.98) Ruler 0.97 (0.95, 0.99) **[Excellent agreement between raters for both methods]**	• Authors do not calculate surface area from ruler method since they say this introduces inaccuracy.
Inter-rater reliability for depth and volume	Insight, eKare	Anghel et al. (2016)	Prospective study (45/NR) Wound type NR	NR	**Depth:** 0.649 (0.441, 0.791) **[Moderate agreement between raters]** **Volume:** 0.696 (0.511, 0.820) **[Moderate agreement between raters]**	• Authors suggest that the shallow nature of the wounds meant assessing depth consistently was difficult.

Abbreviations: DWA=Digital Wound Assessment; ICC=Intraclass correlation statistics (<0.5 indicates poor agreement, 0.5 to 0.75 indicates moderate agreement, 0.75 to 0.9 indicates good agreement and > 0.9 indicates excellent agreement); IQR=Inter-quartile range; LoA=Limits of agreement; MDC=Minimal detectable change; NR=not reported; r^2=Pearson's correlation; SD=Standard deviation; SEm=Standard error of measurement;

[1]It was not usually clear which method was used to obtain wound dimensions.

Table A4 – Concurrent validity for digital wound image measurements

Reference measure	DWMS technology	Evidence source (s)	Study design (wounds/ images) Wound type	Wound dimensions[1]	Results (ICC unless otherwise indicated) [Interpretation]	Comments on reliability
Ruler (Surface area; length; width)	Insight, eKare	Aarts et al. (2023)	Prospective study (52/52) Surgical HS wounds	Median (IQR) surface area: 10.1 (5.8–23.3) cm² Mean (range) surface area: 18.7 (2.5 to 95.8) cm²	**Surface area:** 0.916 (0.857, 0.951) **Length:** 0.244 (-0.022, 0.482) **[Excellent agreement between methods for surface area. Very poor for length measurements]**	• Dr Aarts speculated that poor agreement for length could be due to the shape of the wounds (typically 5cm long and 1.5cm wide) [Personal communication]
		Anghel et al. (2016)	Prospective study (45/NR) Wound type NR	NR	Correlation (r) **Surface area:** 0.996, p<0.001 **Length;** 0.990, p<0.001 **Width:** 0.987, p<0.001 **[Excellent correlation between methods]** Difference between medians (Wilcoxon signed rank test) Surface area, p<0.001 Length, p=0.473 Width, p=0.119 **[Results obtained for median surface area were different between methods]**	• Authors comment that the device was unable to accurately measure wounds <4cm².
Planimetry (Surface area; length; width)	Insight, eKare	Aarts et al. (2023)	Prospective study (52/52) Surgical HS wounds	Surface area Median (IQR): 10.1 (5.8–23.3) cm² Mean (range): 18.7 (2.5 to 95.8) cm²	**Surface area**: 0.987 (95% CI 0.977–0.992) Mean difference (LoA) 0.97 (-6.1, 8.1) cm² Systematic bias: -0.11 cm² **[Authors' concluded that overall, this shows excellent concurrent validity]**	• Manual planimetry. • No predefined LoA.
		Jun et al. (2019)	Retrospective study (26/232)	Surface area (mean (sd)): 37.14 (41.47) cm²	**Reference vs DWA (mean (sd))** **Surface area** (cm²): 37.14 (41.47) vs 36.95 (39.54), p=0.838 Length (cm): 6.20±4.13 vs 5.91±3.90, p=0.155	• Digital planimetry. • No predefined LoA, but authors comment that the ranges obtained

Reference measure	DWMS technology	Evidence source (s)	Study design (wounds/images) Wound type	Wound dimensions[1]	Results (ICC unless otherwise indicated) [Interpretation]	Comments on reliability
			Surgically debrided pressure ulcers		Width (cm): 5.85 (3.97) vs 5.88 (4.21), p=0.863 [No evidence for a difference in means between methods] Bland Altman plots showed no systematic bias for wounds of different sizes. Bland Altman: mean difference (sd), LoA Surface area (cm^2): 0.19 (4.64), -8.91, 9.29 Length (cm): 0.28 (0.98), -1.63, 2.19 Width (cm): -0.03 (0.90), -1.80, 1.74 [LoA are wide, given the size of the wounds] **[Authors' conclusion was that there is evidence that the methods do not show good agreement]**	seemed disproportionately large for the size of wounds. • Authors comment that patients with pressure ulcers often cannot maintain steady positions for long enough for standard wound assessment photography, leading to errors. • Use of planimetry prevents changes in position from affecting assessment.
		Toygar et al. (2020)	Prospective study (20/20) Diabetes related foot ulcer	Surface area (mean) DWA: 6.32 cm^2 Manual planimetry: 6.41 cm^2 Digital planimetry: 6.32 cm^2 Range: 0.10cm^2 to 23.74cm^2.	**Surface area** Manual planimetry: 0.970 (0.880–0.994) Digital planimetry: 0.970 (0.872–0.992) Manual planimetry: CCC= 0.925 (0.825–0.968) Digital planimetry: CCC= 0.926 (0.826–0.969) **[Excellent agreement between methods]** Mean difference (LoA) (log transformed data) Manual planimetry: -0.2 (-5.5, 5.2) Digital planimetry: 0.1 (-1.0, 1.3) **[Authors' conclusion was there were no difference between DWMS and manual or digital planimetry, especially in wounds <10cm^2]**	• Manual and digital planimetry • No predefined LoA. • 7 wounds excluded due to highly irregular boundaries, however all included wounds did have some irregularity. • Authors reported increased variation between measurements with larger wounds due to the difficulty in photographing the entire wound area as they became larger and curved.

Reference measure	DWMS technology	Evidence source (s)	Study design (wounds/ images) Wound type	Wound dimensions[1]	Results (ICC unless otherwise indicated) [Interpretation]	Comments on reliability
		Anghel et al. (2016)	Prospective study (45/NR) Wound type NR	NR	**Surface area**: r=0.977, p<0.001 **Length;** r=0.977, p<0.001 **Width**: r=0.988, p<0.001 **[Excellent correlation between methods]** Difference between medians (Wilcoxon signed rank test) Surface area, p=0.911 Length, p=0.001 Width, p=0.001 **[Results obtained for median length and width were different between methods]**	• Digital planimetry • Authors comment that the device was unable to accurately measure wounds <4cm². • The DWA tended to produce greater width and smaller length measurements.
	Tissue Analytics, Net Health	Fong et al. (2023)	Prospective study (358/2334) Venous leg ulcers	Surface area (mean (sd)) DWA on iOS: 6.18 (7.99) cm² DWA on Android: 6.38 (8.30) cm² By planimetry: 9.13 (12.89) cm²	**Surface area** On iOS: 0.799 (0.678, 0.866) On Android: 0.803 (0.701, 0.864) **Length** On iOS: 0.919 (0.840, 0.953) On Android: 0.914 (0.843, 0.947) **Width** On iOS: 0.846 (0.789, 0.885) On Android: 0.855 (0.808, 0.890) **[Good to excellent agreement between methods]**	• Manual planimetry • Stratification by ethnicity (Chinese, Malay, Indian) found that agreement was lower for ethnicities with darker skin tones (0.647 (0.326, 0.828) for 'other' to 0.883 (95% CI: 0.815-0.922) for Chinese - full data available in the paper)
	Cares4Wounds, Tetsuyu	Chan et al. (2022)	Prospective study (75/547) Diabetes related foot ulcers	Surface area (median (IQR): 3.10 (0.60–14.84) cm²	**Surface area** iPhone 8 Plus: 0.872 (0.794, 0.920) iPhone 11 Pro: 0.932 (0.893, 0.957) iPhoneXS: 0.923 (0.878, 0.952) **Length** iPhone 8 Plus: 0.825 (0.714–0.892) iPhone 11 Pro: 0.934 (0.885–0.961) iPhoneXS: 0.915 (95% CI 0.857, 0.948) **Width** iPhone 8 Plus: 0.825 (0.737–0.886)	• Manual planimetry. • 128 images not included due to poor imaging technique.

Reference measure	DWMS technology	Evidence source (s)	Study design (wounds/ images) Wound type	Wound dimensions[1]	Results (ICC unless otherwise indicated) [Interpretation]	Comments on reliability
					iPhone 11 Pro: 0.930 (0.892–0.955) iPhoneXS: 0.908 (0.858–0.941) **[Good agreement between methods when running on iPhone 8 Plus, excellent agreement for iPhone 11 and XS]**	
	Wound Viewer, Omnidermal	Zoppo et al. (2020)	Prospective study (150/600) Lower limb ulcers, diabetes related foot ulcer, pressure ulcers	Surface area (median (IQR): 5.5 (2.9, 14.1) cm²	Reference vs DWA (median (IQR)) cm² **Surface area:** 5.5 (2.9, 14.1) vs 6.1 (2.9, 14.5) Weibull distribution DWA shape; scale: 0.9475; 10.2809 Planimetry shape; scale: 0.9316; 10.4722 Kruskal-Wallis one-way ANOVA, p>0.9 **[Shows agreement between methods]**	• Statistical analysis compared distribution curves.
Cotton swab (Depth)	eKare, Insight	Jun et al. (2019)	Retrospective study	Depth (mean (sd): 1.53 (1.46) cm	Reference vs DWA (mean (sd) cm) 1.53 (1.46) vs 0.84 (0.75), p<0.001 [Good evidence for a difference in means between measures] Bland Altman plots showed differences between measures increased with larger wounds. Bland Altman mean difference (sd), LoA (cm) 0.69 (0.75), -0.78, 2.16 [LoA are wide, given the size of the wounds] **[Overall, there is no evidence for agreement between measures for depth]**	• Authors suggest that irregularly shaped wounds, with surface tissue that obscure the deepest point of the wound cannot be measured using DWA.
	Wound Viewer, Omnidermal	Zoppo et al. (2020)	Prospective study (150/600)	Depth (median (IQR): 1.93 (1.0, 3.0) cm	Reference vs DWA (median (IQR) cm) 1.9 (1.0, 3.0) vs 2.1 (1.7, 3.2) Authors report that the distribution of scaled probe measurements was too irregular to allow comparison with distribution of DWA.	• Statistical analysis compared distribution curves rather than using ICC.

Reference measure	DWMS technology	Evidence source (s)	Study design (wounds/ images) Wound type	Wound dimensions[1]	Results (ICC unless otherwise indicated) [Interpretation]	Comments on reliability
Saline filling (Volume)	eKare, Insight	Jun et al. (2019)	Retrospective study (26/232)	Volume (mean (sd): 88.92 (145.06) cm^3	Reference vs DWA (mean (sd)cm^3) 88.92 (145.06) vs 20.13 (31.73), p=0.005 **[Good evidence for a difference in means between measures]** Bland Altman plots showed differences between measures increased with larger wounds. Bland Altman mean difference (sd), LoA Volume (cm^3): 68.79 (115.22), -157.04, 294.63 [LoA are wide, given the size of the wounds] **[Overall, there is no evidence for agreement between measures]**	• Authors suggest that volume of irregularly shaped wounds, with surface tissue that obscure the deepest point of the wound cannot be measured using DWA.
Wound Bed Score	Wound Viewer, Omnidermal	Zoppo et al. (2020)	Prospective study (150/600) Lower limb ulcers, diabetes related foot ulcer, pressure ulcers	NA	WBS: agreement between DWA and visual assessment = 96% **[Excellent agreement between methods]**	• Statistical analysis compared distribution curves rather than using ICC.

Abbreviations: CCC, Concordance correlation coefficient; DWA, Digital Wound Assessment; ICC, Intraclass correlation statistics (<0.5 indicates poor agreement, 0.5 to 0.75 indicates moderate agreement, 0.75 to 0.9 indicates good agreement and > 0.9 indicates excellent agreement); LoA, limits of agreement; MDC, Minimal detectable change; sd, Standard deviation; SEm, Standard error of measurement; WBS, Wound bed Score

[1]It was not usually clear which method was used to obtain wound dimensions.

Appendix 5 – List of excluded devices and systems

- Dermicus Wound
- Eykona wound
- Healico
- how2track
- Imito Wound
- InterPIP
- Isla Care
- Mavis
- Mobile Wound Analyzer
- mPOWER
- MyFootCare
- Silhouette
- Wound Care Buddy
- Wound Compass Clinical Support App
- Wound Desk
- Wound Healing Analyzing Tool (WHAT)
- WoundMatrix

- WoundAide (Konica Minolta)
    - Eligible DWMS with validation data, but HTW researchers were unable to find evidence that the system still exists, and experts were unaware of the system. We therefore excluded it.