Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number:	TER410/411
Topic:	Digital tools for the management of wounds
Summary of findings:	Digital wound management can include the use of a smartphone camera with an application and artificial intelligence to help healthcare professionals measure and assess wounds. Data are uploaded for integration with a patient's medical record. We received submissions for two technologies: Minuteful for Wound and Isla. Data for a small number of utilisation and service-related outcomes for these technologies either came from unpublished case studies or published preliminary data. Randomised controlled trials and cohort studies suggest that digital wound management may have a beneficial effect on clinical and cost outcomes compared to face-to-face consultations. However, the studies were heterogeneous in terms of wound aetiology and the intervention used, and none of the published studies included Minuteful for Wound or Isla. It is unclear how generalisable the economic evidence we identified is to NHS Wales. Clarity is needed on the scope should this progress to full assessment, particularly as digital wound management solutions differ in their capabilities.

Introduction and aims

In 2017/2018, an estimated 3.8 million people in the UK were being treated for wounds, which equates to a 71% increase in the annual prevalence of wounds since 2012/2013 (Guest 2020). The total annual NHS cost of managing 3.8 million patents with a wound was an estimated £8.3 billion, which was a 48% increase since 2012/2013 (Guest 2021). People living with wounds are usually already vulnerable, chronically ill or older people, whose physical and mental wellbeing diminish further as a result. Currently, healthcare professionals use paper rulers and may trace the outlines of a wound to measure it. Manual documentation may present issues in terms of accuracy and time. Digital solutions may improve accuracy and allow for remote assessment, reducing the need for patients to visit healthcare professionals.

There are two types of teledermatological consult modalities: the 'store-and-forward' technique is a process in which patient information, such as a photograph and background information, is sent as digital files to a clinician who reviews the data hours or days later. Unlike the store-and-forward modality, the real-time interactive option consists of a video-conference event in which patient and doctor interact at the same time in separate locations. This TER will focus on store-and-forward technologies. There are different types of digital wound management solutions within this modality, with different capabilities.

Two devices were submitted to us by topic proposers:

- Minuteful for Wound (MfW), created by Healthy.io, is a CE-marked specialist digital wound care solution. The solution is comprised of three elements:
  - A point of care application (app), used with a smartphone or tablet and two calibration stickers. The app automatically measures the area of a wound and wound bed tissue types and enables the user to document their assessment using inbuilt best-practice wound assessment flows specific to different wound types.
  - A virtual portal where clinicians can have full oversight of the wound caseload to optimise treatment plans.
  - A business-intelligence dashboard with clinical and operational data insight to support efficiency and identify treatment gaps.

  Data are stored using Cloud technology and can be integrated with electronic patient management systems, including transfer of the full assessment, wound image and associated SNOMED CT codes.
- Isla (IslaCare Ltd.) is a wound management device that does not currently have a CE mark. It does not need to be downloaded as an app as it is available over the internet. All data are securely saved on encrypted cloud servers and not stored on personal devices. Data can be submitted by patients or clinicians.

Health Technology Wales researchers searched for evidence on the digital management of wounds using the store-and-forward technique, including, but not limited to, MfW and Isla.

Evidence overview

The technologies used for the digital management of wounds are digital health technologies, determined to be Tier C technology according to the Evidence Standards Framework for Digital Health Technologies. Technologies within this classification will provide information that will be used to aid treatment or diagnosis, to triage or identify early signs of a disease or condition, or will be used to guide next diagnostics or next treatment interventions. For technologies of this classification, it is recommended that satisfactory evidence is produced to demonstrate effectiveness of the

technology. This includes studies conducted in a setting similar to the UK health and care system, peer-reviewed studies and prospective studies. Evidence to support the claimed benefits of the digital health technology should include real-world evaluations of its clinical utility, and include one or more high-quality studies that support the claimed benefits of the digital health technology in a relevant setting, showing improvements in relevant outcomes. Similarly, appropriate assessment of the economics of the digital health technology should be undertaken.

Guidance and standards

The National Wound Care Strategy Programme (NWCSP), commissioned by NHS England and NHS Improvement, and delivered by the Academic Health Science Network, recommended that NHS-compliant digital technology should be used to capture images of the wound in the clinical care of wounds of the lower limb (NWCSP 2020) and surgical wounds (NWCSP 2021a). NWCSP published a functional overview, which provides 'what good looks like' with regards to the functionality of wound management digital systems (NWCSP 2021b). Additionally, NWCSP provides a summary of attributes required for mobile technology and data information for wound management (NWCSP Implementation Case).

Secondary evidence

Scottish Health Technologies Group (SHTG) (2021) published an Innovative Medical Technology Overview on the Scottish asynchronous digital dermatology appointment service (DDAS). The DDAS is an online dermatology clinic which allows patients to submit images of their skin condition via a smartphone or computer, along with answers to specific questions about their skin condition, to a dermatology specialist. From March to June 2020, 405 digital appointments were completed for people needing an urgent dermatology referral, of which 72% had potentially cancerous skin lesions and 28% had inflammatory dermatoses. Clinicians reported that 80% of the images submitted by patients were of sufficient quality for assessment. The average DDAS appointment time of 10 minutes was 3 minutes shorter than the average face-to-face consultation time. As well as patients reporting DDAS as being easy to use, the need for them to travel and take time off work to attend appointments generally reduced. There are costs associated with setting up the DDAS, plus additional annual and maintenance costs. NHS Scotland is currently charged £3 per DDAS appointment.

Canada's Drug and Health Technology Agency Rapid Response Report: Summary of Abstracts (2020) included 13 non-randomised studies and found that store-and-forward and face-to-face consultations were comparable in diagnostic accuracy and clinical effectiveness.

A meta-analysis by Chen et al. (2020), comparing different telemedicine methods to standard care, included six randomised controlled trials (RCTs) and six cohort studies (3,913 patients). Of these, only four studies (including two RCTs) used tablet or mobile phone apps, whereas other studies used email, telephone, and videoconferencing. There were no significant differences in wound healing at final follow-up (between 3 and 35 months across studies), wound healing at one-year, or mortality rate. However, there was a decreased risk of amputation at one-year in patients receiving telemedicine (risk ratio: 0.45, 95% confidence interval [CI]: 0.29 to 0.71). One of the studies using a phone or tablet evaluated patient satisfaction, and reported no statistically significant difference between the two groups (mean difference: 0.07, 95% CI: −0.10 to 0.24).

A systematic review by Ng et al. (2022) assessed the accuracy of using telemedicine in the diagnosis of surgical site infections (SSI) in post-surgical adults compared to in-person assessments. One of

the six studies included in the systematic review involved 47 patients using a mobile app (WoundCheck) to send wound images to clinicians. The SSI detection rate of this study was 87.5% after a follow-up of 14 days.

A qualitative systematic review by Foong et al. (2020), on the role of digital management of diabetic foot ulcers, reported that most patients felt that digital interventions with wound image-taking capabilities would be useful as they checked their feet daily. Patients perceived that the image-taking feature of the mobile phone application mHealth solved the difficulty they previously felt taking wound images. However, some patients with decreased mobility found it difficult to take the image of their wound properly.

Primary evidence

HTW researchers identified unpublished case studies and/or published preliminary results for the MfW and Isla technologies, submitted by topic proposers. We also identified two published primary studies for the Swift mobile phone app, one study for the WOUND COMPASS Clinical Support App, and one study for the Tissue Analytics app for the management of wounds. All primary evidence reported on utilisation and service-related outcomes; they did not report direct patient outcomes comparing digital tools to standard care.

In a published preliminary study by Wynn and Scholes (2022), MfW was trialled over seven months in an acute inpatient setting in Northwest England. When comparing before and after the use of MfW, there was a 37% increase in the availability of wound photography and a 10% reduction in inappropriate tissue viability nurse reviews. Challenges noted during the implementation of the app included initial software compatibility issues with the available tablets and poor staff engagement.

Unpublished data from October 2021 to February 2023 in Swansea Bay University Health Board (community setting) showed: 158 clinicians were using MfW, 1,734 patients were assessed, 3,217 wounds were assessed, 21,697 assessments were completed on wounds, 1,061 wounds were marked as healed by clinicians, and 182 were marked as infected wounds. From December 2021 to May 2022 in Swansea Bay University Health Board, patients reported that they were 'extremely motivated' to improve their wound after seeing their wound progression using MfW. Of the 10 clinicians who completed a survey, 80% indicated the 'ability to identify deteriorating wounds earlier' as one of the main benefits of MfW.

The preliminary findings of the Collaborative for Surgical Site Infection Surveillance project compared surgical wound healing in 2,116 patients from five different hospitals in England, using telephone follow-up, using postal questionnaires and contacting non-responders by telephone, asking patients to install a postoperative app on their personal smartphone (Medopad, Huma), and using an SSI surveillance text link which did not need to be installed (Isla). The group of patients who were asked to install an app on their smart device had the lowest return rate for information on their wound (9.8%), whilst Isla had the second highest return rate of 84.5%, with a 5.7% difference to the most preferred solution of telephone follow-up (Alwis et al. 2022).

In a cohort study of 87 people with diabetic foot ulcers, venous insufficiency and pressure ulcers, a mobile phone app (Swift) was more reliable at measuring wound area than the traditional paper-ruler method (intraclass correlation coefficient: 0.97 to 1.00 compared to 0.92 to 0.97, respectively) (Wang et al. 2017). Mohammed et al (2022) also assessed the Swift app (which utilises AI), but they compared it to manual methods (photographic image of the wound using a digital camera, a paper-ruler, and a depth probe to determine the key measurements of the wounds). A total of 91 patients with diabetic ulcers, venous stasis, arterial ulcers, pressure ulcers, surgical wounds, skin tears,

abscesses, blisters, and burns were included in the study. The average time to capture and access wound image with the AI digital tool was significantly faster than a standard digital camera, with an average of 62 seconds. Overall, the average time to complete a wound assessment using Swift was significantly faster than manual methods, by 79%. Moreover, acquiring an acceptable wound image was significantly more likely to be achieved the first time using the Swift tool than the manual methods (92.2% compared to 75.7%, respectively).

Real-world data, mainly from England, on the WOUND COMPASS Clinical Support App reported that 100% of wound specialists and 82% of non-wound specialists felt more confident and competent in wound assessment using the WOUND COMPASS Clinical Support App compared to standard care alone. Additionally, practice variation was reduced due to greater compliance to their local formulary (100% compliance in wound specialists and 79% compliance in non-wound specialists) (Moore et al. 2022).

An Australian study compared 243 wounds assessed with standard care to 184 wounds assessed with the Tissue Analytics app. Compared to standard care, wound documentation in the Tissue Analytics digital app group improved significantly (more than two items documented: 24% versus 70%, respectively). During use of the Tissue Analytics digital app, 101 out of 132 wounds improved (mean wound size reduction: 53.99%). Wound improvement with standard care was not reported (Barakat-Johnson et al. 2021).

Economic evidence

One systematic review of economic evaluations and one additional economic evaluation were identified in Canada's Drug and Health Technology Agency Rapid Response Report: Summary of Abstracts (2020), which reported that store-and-forward technology in a topical clinical setting can be cost effective when used as a triage mechanism and for patients required to travel a far distance, compared to conventional face-to-face care. Teledermatology had a mean expected cost savings of $10.00 to $52.65 per consult. The authors of the economic evaluation also found that through the use of teledermatology, 27% of in-person consults and 3.29% of emergency room visits were avoided. However, the dermatological conditions of the patients and the exact type of store-and-forward technology used in each study included are uncertain.

In the systematic review by Chen et al. (2020) an economic evaluation reported that telemedicine follow-up was US $2,300 less per patient compared with face-to-face consultation, but the difference was not statistically significant. Another two studies also revealed reduced cost. One study revealed a higher mean total cost per patient because of larger and more severe ulcers in the telemedine group. Whilst all of these studies used photos of the wound, none of them came from a smartphone or tablet.

The topic proposer for MfW estimates that potential savings in nursing time and resource from reducing visits could be over £4 million per year. The topic proposer states that if healing time reduces even by 10%, this will save an additional 1,906 visits a month.

Ongoing guidance

Currently, universal imaging standards have not been developed, validated, and adopted. At the time of writing this report, the Professional Records Standards Body is producing a wound care information standard, which will include the assessment, management and maintenance prevention of wound care for lower limb (leg and foot) wounds, pressure ulcers and surgical wounds

in the UK. This standard is anticipated to be published in August 2023. NWCSP is producing recommended specifications for mobile digital technology apps suitable for wound care, but it is unclear when these will be published. Additionally, the International Society for Digital Imaging of the Skin is working toward the development of digital imaging standards, but it is unclear when they will be published.

Ongoing studies

The topic proposer states that the next phase of the MfW pilot in Swansea Bay University Health Board will focus on its use in podiatry, the Pressure Ulcer Prevention Intervention Service, and microbiology.

An SHTG Assessment, due to be published in 2023, will assess capture-store-and-forward photo triage (taken by patients, GPs, medical photographers) for primary care referrals, compared to written descriptive referrals without photo-documentation. Whilst it will cover all areas of dermatology, it will focus on the need for patients with skin cancer to access rapid diagnosis. Outcomes will include: waiting times for all referred conditions, time to treatment/advice/reassurance, number of face-to-face specialist consultations, proportion of referrals managed virtually, proportion redirected (from secondary care dermatology) to specific pathways, quality of life, patient/clinician satisfaction, safety, and cost effectiveness.

In addition, we identified a mixed-methods systematic review from Hewitt et al. investigating digital health interventions to support the health and well-being of people living with long-term dermatological conditions. This study will be based in Wales and England and has an anticipated publication date of April 2022 (at the time of this report, it hasn't been published). It is unclear what dermatological conditions and digital health interventions will be included.

Areas of uncertainty

The evidence for the specific technologies submitted by the topic proposers comes from unpublished case studies and/or published preliminary data. This does not appear to include effectiveness on direct patient outcomes compared to standard care, such as accuracy of wound measurement, healing rates, incidents of patient harm, changes in patient management, and ability to monitor wounds remotely. Whilst RCTs and cohort studies were identified for other digital wound management solutions, is unclear how these differ from one another, and many different types of wound aetiologies were included in the studies. If this topic proceeded to a full assessment, there would need to be more clarity over the exact scope, including the type of wound and the type of digital wound management solution. It is unclear whether the published economic evidence identified can be generalisable to the technologies used in NHS Wales.

Literature search results

Health technology assessments and guidance

CADTH (2020). Rapid Response. Summary of abstracts: Asynchronous Teledermatology Consultations Using Store-and-Forward Technology: Diagnostic Accuracy, Clinical Utility, and Cost-Effectiveness; https://www.cadth.ca/asynchronous-teledermatology-consultations-using-store-and-forward-technology-diagnostic-accuracy

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National Wound Care Strategy Programme (NWCSP). 2021a. Surgical Wound Recommendations: https://www.nationalwoundcarestrategy.net/nwcsp-publications-and-resources/

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National Wound Care Strategy Programme (NWCSP). 2020. NWCSP Recommendations for Lower Limb: https://www.nationalwoundcarestrategy.net/nwcsp-publications-and-resources/

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Mobile phone attributes are described in Appendix 1

Evidence reviews and economic evaluations

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Individual studies

Mohammed, H.T., Bartlett, R.L., Babb, D., Fraser, R.D. and Mannion, D., 2022. A time motion study of manual versus artificial intelligence methods for wound assessment. Plos one, 17(7), p.e0271742: https://doi.org/10.1371/journal.pone.0271742

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Wynn M, Scholes L (2022). Trial of the Minuteful mobile application for wound care in an inpatient setting. Wounds UK: https://www.wounds-uk.com/journals/issue/666/article-details/trial-minuteful-mobile-application-wound-care-inpatient-setting

Zhang, J., Mihai, C., Tüshaus, L., Scebba, G., Distler, O. and Karlen, W., 2021. Wound image quality from a mobile health tool for home-based chronic wound management with real-time quality feedback: Randomized feasibility study. *JMIR mHealth and uHealth*, *9*(7), p.e26149: doi:10.2196/26149

Ongoing research

Hewitt R, Purcell C, Gillen E, Ridd M, Pattinson R, Wren G, Jones B, Hughes O, Ploszajski M, Bundy C. Digital health interventions to support the health and well-being of people living with long-term dermatological conditions: a mixed-methods systematic review: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=285435

Professional Record Standards Body. Wound care information standard. Expected publication date: early August 2023: https://theprsb.org/woundcare/

Scottish Health Technologies Group. Capture-store-and-forward photo triage for primary care dermatology referrals. SHTG Assessment. Expected publication date: 27 January 2023: https://shtg.scot/our-advice/capture-store-and-forward-photo-triage-for-primary-care-dermatology-referrals/

Evidence supplied by topic proposer

Alwis, S., Asadi, N., Bagona, L., Bhudia, S.K., Birdsall, D.M., Brady, D., Brown, C., Chieng, S., Connolly, K., Derland, S. and English, C., 2022. Implementing smartphone technology in practice using the Collaborative for Surgical Site Infection Surveillance (CASSIS) project: preliminary findings. Wounds UK, 18(1): https://www.wounds-uk.com/journals/issue/657/article-details/implementing-smartphone-technology-practice-using-collaborative-surgical-site-infection-surveillance-cassis-project-preliminary-findings

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Moore ZEH, Aynge GE, Carr CG, Horton AJ, Jones HA, Murphy NS, Payne MR, McCarthy CH, Murdoch JM (2022). A Clinical Support App for routine wound management: reducing practice variation, improving clinician confidence and increasing formulary compliance. International Wound Journal; 19(5): 1263-1275: https://doi.org/10.1111/iwj.13868

Date of search:	November 2022 (MfW data updated February 2023)
Concepts used:	Minuteful for Wound, MfW, Isla, digital wound/ulcer management, teledermatology, postoperative application (app), Medopad, Huma, MHealth, wound measurement, WoundCheck