Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report [1]

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	TER508
Topic	Optical sensor devices for the detection of infiltration and extravasation of intravenous fluid
Summary of findings	Extravasation and infiltration are the inadvertent leaking of intravenous (IV) fluid from the intended vein into the surrounding tissue, which can lead to discomfort or tissue damage. These are currently monitored for by regular assessment of IV insertion sites by clinicians. Optical sensor devices can continuously monitor these sites, alerting clinicians when an event occurs. The ivWatch was the only commercially available device identified in the literature. One scoping review was identified that included two observational studies and one conference abstract on the use of ivWatch. Another two observational studies were identified and one ongoing randomised controlled trial. The identified studies found the sensitivity of ivWatch for detecting infiltration/extravasation was generally high, ranging from 78.3% to 100%. Only one study reported the specificity and overall accuracy; these were found to be 83% to 86.3% and 65% to 77.3%, respectively. ivWatch was reported to detect infiltration/extravasation events earlier than routine clinician assessment, ranging from an average of 6 hours to 32 hours earlier detection. No economic evidence was identified. There was a lack of randomisation in the included studies and sample sizes were small. The majority of evidence is from infants and the only study on adults was reported in a conference abstract. There is a lack of variety in the outcomes reported and it is uncertain what clinical outcomes may be of importance when assessing this technology. There is also potential for subjectivity and variation in the reference standard for diagnosing these conditions.

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

Introduction and aims

Extravasation and infiltration are the inadvertent leaking of intravenous (IV) fluid from the intended vein into the surrounding tissue (Kamada et al. 2023). If the leaking fluid is a vesicant (an agent that can cause blistering) this is termed extravasation and if it is a non-vesicant, then it is called infiltration. Extravasation/infiltration events can lead to a variety of negative consequences such as swelling, pain, cytotoxicity, necrosis, nerve damage, or compartment syndrome (Doellman and Rineair 2016; Kamada et al. 2023). Delayed detection may lead to tissue damage requiring longer hospital stays and potential surgical intervention. NHS Resolution received 444 claims related to extravasation injuries between April 2011 and March 2021, resulting in 197 claims settled with damages costing the NHS £15.6 million (NHS Resolution 2023).

Standard of care for monitoring peripheral IV insertion sites for infiltration or extravasation is routine assessment by clinicians at regular intervals for signs such as swelling, redness, change in temperature, and pain at the site. The frequency of these examinations may vary depending on patient characteristics and the type of IV infusion the patient is receiving, but also organisational factors such as staffing levels. However, assessment in this way may occur after IV fluid has been leaking for some time and tissue damage is already occurring.

Optical sensor devices are a non-invasive way to continuously monitor tissue next to an IV insertion site to detect the early signs of infiltration or extravasation. The device is placed on the skin and uses visible and near-infrared light to assess the optical properties of the underlying tissue. It receives reflected light signals back and uses an algorithm to determine if changes in the signals are consistent with an early infiltration or extravasation event. The ivWatch Model 400 Patient Monitoring System was the only such device that was identified in the literature that was commercially available. The device emits visual and audible notifications to alert clinicians to the infiltration/extravasation event potentially earlier than any clinical signs can be observed and before damage has occurred. A yellow notification indicates a “possible infiltration/extravasation event” and a red notification indicates a “probable event” (Doellman and Rineair 2016).

Health Technology Wales researchers searched for evidence on the clinical and cost effectiveness of optical sensor devices for the detection of infiltration and extravasation of intravenous fluid.

Evidence overview

HTA/Guidance

No health technology assessments (HTAs) or current guidance was identified that examined optical sensor devices or methods for monitoring IV catheter sites for infiltration or extravasation.

Secondary evidence

One scoping review on infiltration/extravasation detection devices was identified. Kamada et al. (2023) included three studies on ivWatch: two observational studies (Doellman and Rineair 2019; van Rens et al. 2019) and one conference abstract (Naramore et al. 2016). This review did not include any evidence synthesis of results and, therefore, these studies will be discussed in the next section.

Primary Evidence

Evidence overview

Doellman and Rineair (2019) investigated the use of ivWatch compared to standard nursing care of hourly checking of IV sites in children aged 0 to 17 years. In the control group (n = 156), where an ivWatch was placed but the alarming function disabled, 18 out of 23 clinician-confirmed infiltrations were detected by the device, resulting in a sensitivity of 78.3% (95% confidence interval [CI] 56.5% to 92.5%). On average, ivWatch issued a yellow notification 32.3 hours (95% CI 17.3 to 47.3) before clinician detection and issued a red notification 29.8 hours (95% CI 14.8 to 44.8) before. In the study group (n = 57), 12 out of 15 clinician-confirmed infiltrations were detected by the device and a warning issued before detection by a clinician. This resulted in a sensitivity of 80% (95% CI 51.9% to 95.7%) in this group.

In a pilot study, van Rens et al. (2019) examined the effectiveness of ivWatch on preterm infants (n = 15). Of 15 infiltration events that occurred, the device detected 14 prior to being confirmed by visual inspection, leading to a sensitivity of 93.3%.

Naramore et al. (2016) reported in a conference abstract that ivWatch was used on 24 adults receiving peripheral IVs, where infiltration was intentionally induced. The device detected 23 of 24 infiltrations resulting in a sensitivity of 95.8%.

In addition, to the three studies included in the scoping review above, two further observational studies were identified.

When examining a neonatal population (n = 21), van Rens et al. (2023) reported that ivWatch detected 11 infiltration/extravasation events resulting in a sensitivity of 100%. All events were detected by the device before being confirmed by a clinician.

D'Andrea et al. (2023) also examined a neonatal population using ivWatch in a two-phase study. The first phase (n = 25) compared the accuracy of detecting infiltrations by ivWatch versus routine nurse assessment, thus the visual and audible notifications of ivWatch were disabled for this phase. In this phase, the sensitivity of ivWatch was found to be 83%, specificity 83%, and overall diagnostic accuracy was 65%. The average detection time (mean ± standard deviation) was 6.2 ± 3 hours earlier with ivWatch than nurse assessment. The second phase (n = 25) involved enabling the notifications from the ivWatch so that nurses could intervene as soon as a notification was made in addition to their routine assessment. The sensitivity was found to be 95.4%, specificity 86.3%, and overall accuracy 77.3% in this phase. On average, ivWatch detected infiltration 6.1 ± 6 hours (mean ± standard deviation) earlier than the emergence of observable clinical signs.

Economic evidence

No economic analyses were identified on the use of optical sensor devices for infiltration/extravasation monitoring.

Ongoing evidence

One protocol for an ongoing randomised controlled trial (RCT) was identified. McBride et al. (2022) are conducting a trial comparing the use of ivWatch to detect extravasation in paediatric intensive care to standard care (clinical observation). According to the trial register entry (ACTRN12620000317998), the last data were collected in November 2022.

The Topic Proposer also provided details of another ongoing RCT (ACTRN12623000561684) that will examine the use of ivWatch in children up to one year of age compared to standard observation. This will include capturing clinical outcomes, quality of life data, and carrying out a cost-utility analysis. Data collection is anticipated to be completed in 2025.

Areas of uncertainty

- There is a lack of randomised trials.
- Sample sizes are generally very small, despite the large numbers of people that undergo IV fluid therapy.
- There is a lack of published, peer-reviewed evidence in adults, with this only currently being reported in a conference abstract. The Topic Proposer has stated more data on adult patients is expected to be available in 2024.
- Most studies only report the sensitivity of the device and no clinical outcome measures are reported. There is uncertainty around what other outcome measures may be important to consider for this technology. The lack of specificity data means there is uncertainty about the rate of "false alarms" from the system.
- The reference standard is generally some variation of routine observation by clinicians and there may be some variability and subjectivity in establishing an infiltration/extravasation event in this way depending on setting and clinician experience.
- No studies reported on adverse events, though one study states there are no expected adverse events from this technology as it is a non-invasive, externally applied intervention.

Literature search results

Health technology assessments and guidance
No evidence found
Evidence reviews and economic evaluations
Kamada S, Mosier R, El-Khalili T, et al. (2023). Scoping review of early intravenous infiltration and extravasation detection devices. J Infus Nurs. 46(2): 97-106. doi: https://doi.org/10.1097/nan.0000000000000499
Individual studies
D'Andrea V, Prontera G, Carlino R, et al. (2023). Optical detection of infiltration during peripheral intravenous infusion in neonates. The Journal of Vascular Access. Online ahead of print: 11297298231177723. doi: https://doi.org/10.1177/11297298231177723 van Rens MFPT, Vijlbrief D, Braun S, et al. (2023). Peripheral intravenous therapy infiltration/extravasation (PIVIE) risks and the potential for earlier notification of events using a novel sensor technology in a neonatal population. The Journal of Vascular Access. 11297298231185536. doi: https://doi.org/10.1177/11297298231185536
Citation searching
The following studies were identified by examining the studies included in Kamada et al. (2023): Doellman D, Rineair S. (2019). The use of optical detection for continuous monitoring of pediatric IV sites. Journal of the Association for Vascular Access. 24(2): 44-7. doi: https://doi.org/10.2309/j.java.2019.002.003 Naramore J, Bonnema G, Schears G. (2016). Optical infiltration detection through an occlusive dressing. Journal of the Association for Vascular Access. 4(21): 255. https://doi.org/10.1016/j.java.2016.10.044 van Rens M, Hugill K, Francia AV. (2019). A new approach for early recognition of peripheral intravenous (PIV) infiltration: A pilot appraisal of a sensor technology in a neonatal population. Vascular Access. 5(2): 38-41. doi: https://doi.org/10.33235/va.5.2.38-41
Ongoing research
McBride CA, Rahiman S, Schlapbach LJ, et al. (2022). Comparing ivWatch biosensor to standard care to identify extravasation injuries in the paediatric intensive care: a protocol for a randomised controlled trial. BMJ Open. 12(2): e047765. doi: https://doi.org/10.1136/bmjopen-2020-047765
Provided by Topic Proposer
NHS Resolution. (2023). Extravasation. NHS Resolution. Available at: https://resolution.nhs.uk/resources/extravasation/ [Accessed 11 Dec 2023].

Date of search	6 November 2023
Concepts used	ivWatch, intravenous, IV, infiltration, extravasation, optical, sensor

Proposed research question and evidence selection criteria (if selected)

Proposed Research question	**What is the clinical and cost effectiveness of optical sensor devices for the detection infiltration and extravasation of intravenous fluid compared to standard care?**

	Inclusion criteria	Exclusion criteria
Population	Patients in healthcare settings undergoing peripheral intravenous infusion therapy	Central intravenous infusion therapy
Intervention	Optical sensor devices, such as ivWatch Model 400 Patient Monitoring System	
Comparison/ Comparators	Standard care: routine assessment by clinicians	
Outcome measures	Diagnostic accuracy (sensitivity, specificity, positive predictive value, negative predictive value) Time to detection of infiltration/extravasation Time to treatment Severity of infiltration/extravasation at time of detection Health-related quality of life Adverse events Economic outcomes	

Proposed speciality	**Blood and immune system**