



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:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Wiresafe device to prevent guidewire retention during central venous catheter placement
Topic exploration report number:	TER272

Introduction and aims

Health Technology Wales researchers searched for evidence on Wiresafe™ and other central line insertion kits to prevent guidewire retention in people undergoing central line placement.

Wiresafe™ is designed to prevent the never event of retained guidewires following central venous catheter (central line) placement. Guidewire retention is associated with a high mortality (up to 20%), arrhythmia, thrombosis, cardiac perforation, and tamponade.

Wiresafe™ is a box with a simple key mechanism which is unlocked by the guidewire itself. As the suture, suture holder and antimicrobial dressings within the box are required to finish the procedure, the procedure cannot be completed without prior removal of the guidewire from the patient. The Wiresafe™ box doubles as a sharps disposal container.

Other solutions to guidewire retention include retraining of staff, checklists, two-person procedures, documentation of guidewire removal, supervising of trainees, ensuring the clinician grips the proximal end of the guidewire, not inserting the guidewire beyond 18cm and checking the trolley. It is unclear what current practice is in Wales for preventing guidewire retention. Different central line insertion kits are used across Wales. The contents within WireSafe™ can be tailored or ordered as an individual procedure pack (including suture, suture holder, scissors, dressings). WireSafe™ could therefore either replace currently used insertion kits, or be used as an adjunct.

Summary of evidence

No guidelines or health technology assessments were identified which considered Wiresafe™ or central line insertion kits to prevent guidewire retention in people undergoing central line placement.

One forced error simulation study (Mariyaselvam et al., 2017 and Mariyaselvam et al., 2019) comprising a replicated catheter insertion with an engineered retained guidewire event

randomised clinicians between standard versus locked packs (Wiresafe™). The study monitored the incidence of guidewire retention at completion of central catheter insertion in both the locked and standard pack groups. It found that guidewires were retrieved in 2/10 (20%) cases in the standard pack group compared with 10/10 (100%) cases in the locked pack group ($p < 0.001$). It reported that in the locked pack group, clinicians who did not immediately recognise the guidewire in the catheter lumen ($n=8$) attempted to complete the procedure but were prevented from doing so when unable to access the contents of the box, which prompted a search for the guidewire (key). The study also included a structured verbal questionnaire to elicit clinician views in the locked pack group. Clinicians reported an 'improved subjective safety of central venous catheter insertion and ... easy disposal of the sharps and guidewire'.

Fenik et al. (2013) considered whether pre-packaged central line kits reduce procedural mistakes during central line catheter insertion on a manikin by novices (final year medical students and recently qualified physicians). Participants were randomised to either a pre-packaged all-inclusive kit or a standard kit containing only the central vein catheter, with all other components provided separately on a materials cart. The procedure was recorded and analysed using a checklist. The pre-packaged kit group had a shorter procedure duration, lower minor and major technical mistakes and higher correct steps. Differences in breaches of aseptic techniques were not statistically significant.

Peh et al. (2016) was a pre- post- study which considered whether a structured educational program and modified central venous catheter set and a drape with reminder stickers would reduce guidewire retention. Internal medicine trainees in the medical intensive care unit and the medical intermediate care area underwent a structured educational program and used a central venous catheter dressing kit which was modified by the inclusion of a sterile drape with reminder stickers which read "REMOVE THE GUIDEWIRE". The study found that no incidences of guidewire retentions occurred after the quality improvement project was initiated, compared with three guidewire retention events during a preceding time period. It reported a cost reduction per use of modified central venous catheter set of \$29.26 (Singaporean Dollars) though it did not report how these costs were calculated (for example, whether the costs of the educational program and the cost of the central venous catheter kit were included).

Areas of uncertainty

It is unclear which insertion kits and which, if any, mechanisms to prevent guidewire retention used in standard care in Wales (e.g. checklists).

The only study in a non-simulated setting considered an educational program and central venous catheter set with reminder stickers. However, given that guidewire retention is a rare event, the Mariyaselvam et al (2017) Wiresafe™ study and Fenik et al (2013) studies using simulations could be considered a pragmatic solution to test the effectiveness of Wiresafe™ and other pre-packaged central line kits.

It is unclear what proportion of guidewire retention 'never events' are due to operator distraction. In a letter to the editor in response to Mariyaselvam et al (2017), Camporesi et al (2018) comment that in their institution between 2011-2013, 25% ($n=2$) of guidewire retentions were caused by operator distraction, whereas 63% ($n=5$) were the result of guidewire fragmentation and 12.5% ($n=1$) was due to the inability to retract the guidewire because of impingement.

Conclusions

No guidelines or secondary evidence was available which considered Wiresafe™ or other central line insertion kits.

Two studies were simulations using Manikin models. One randomised study compared Wiresafe™ with standard packs, while the second randomised study compared pre-packaged all-inclusive boxes (which did not feature the lock mechanism of the Wiresafe box) with standard kit containing only the central vein catheter.

One pre-post study in the intensive and intermediate care settings considered a structured educational program and a modified central venous catheter set and a drape with reminder stickers. This modified system did not feature the lock mechanism of the Wiresafe™ box. The study reported a cost reduction per use of modified central venous catheter set of \$29.26 (Singaporean Dollars), though it did not report how these costs were calculated.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant evidence from this source
Health Technology Assessment Group	We did not identify any relevant evidence from this source
Health Information and Quality Authority	We did not identify any relevant evidence from this source
EUnetHTA	We did not identify any relevant evidence from this source
International HTA Database	We did not identify any relevant evidence from this source
UK guidelines and guidance	
SIGN	We did not identify any relevant evidence from this source
NICE	We did not identify any relevant evidence from this source
Secondary literature and economic evaluations	
https://www.epistemonikos.org/en/	We did not identify any relevant evidence from this source
Cochrane library	We did not identify any relevant evidence from this source
Medline (via Ovid or Pubmed)	We did not identify any relevant evidence from this source
Primary studies	
Cochrane library	<ul style="list-style-type: none"> Fenik, Y., Celebi, N., Wagner, R. <i>et al.</i> Prepackaged central line kits reduce procedural mistakes during central line insertion: a randomized controlled prospective trial. <i>BMC Med Educ</i> 13, 60 (2013). doi: https://dx.doi.org/10.1186%2F1472-6920-13-60
Medline	<ul style="list-style-type: none"> Peh WM, Loh WJ, Phua GC, Loo CM. Eliminating guidewire retention during ultrasound guided central venous catheter insertion via an educational program, a modified CVC set, and a drape with reminder stickers. <i>BMJ Qual Improv Rep.</i> 2016 Feb 12;5(1):u209550.w3941. doi: https://dx.doi.org/10.1136%2Fbmjquality.u209550.w3941 Camporesi E, Enten G, Omar HR, Mangar D. Modeling the Effects of the Locked Pack Procedure to Prevent Guidewire Retention in a Clinical Setting. <i>Anesthesiology.</i> 2018 Aug;129(2):371. doi: 10.1097/ALN.0000000000002308
Ongoing primary or secondary research	
PROSPERO database	We did not identify any relevant evidence from this source
<i>Check for recent systematic review protocols.</i>	
Clinicaltrials.gov	We did not identify any relevant evidence from this source
Other	
Evidence from topic proposer	<ul style="list-style-type: none"> Mariyaselvam MZA, Catchpole KR, Menon DK, Gupta AK, Young PJ. Preventing Retained Central Venous Catheter Guidewires: A Randomized Controlled Simulation Study Using a Human Factors Approach. <i>Anesthesiology.</i> 2017 Oct;127(4):658-665. doi: https://doi.org/10.1097/ALN.0000000000001797 Mariyaselvam M., Pearson D., Heij R., Fawzy E., Young P. (2019) The WireSafe™ for Preventing Retained Central Venous Catheter Guidewires: Clinical Usability. In: Lightner N. (eds) <i>Advances in</i>

	Human Factors and Ergonomics in Healthcare and Medical Devices. AHFE 2018. Advances in Intelligent Systems and Computing, vol 779. Springer, Cham. https://doi.org/10.1007/978-3-319-94373-2_27
http://klipsuk.com/	<ul style="list-style-type: none"> Oxford Academic Health Science Network. The Wiresafe Implementation Support Pack for Provider Organisations. Published date: September 2017. http://klipsuk.com/wp-content/uploads/2017/02/WireSafe-Implementation-Pack-v4.0.pdf

Date of search:	May 2021
Concepts used:	Wiresafe, guidewire, guidewire retention, central line insertion kit, insertion kit