Kurin Lock for blood culture collection

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Kurin Lock. It is used for collecting blood samples for blood culture.
- The **innovative aspects** are that the technology diverts and isolates the first flash (about 0.15 ml) of blood, which may contain contaminants that can lead to a false-positive blood culture result.
- The intended **place in therapy** would be when samples for blood culture are needed, as an alternative to standard collection methods.
- The **main points from the evidence** summarised in this briefing are from 7 non-randomised studies including at least 6,075 blood samples analysed. They show that Kurin Lock can reduce the rates of false-positive blood cultures.
- **Key uncertainties** around the evidence or technology are that there is limited published evidence and most of it is not from the NHS.
- **Experts advised** that the technology is novel and likely to produce system benefits, but that there are some uncertainties around cost–benefit and efficacy.

- The cost of Kurin Lock is £18 per unit (excluding VAT). The cost of standard care is about £1.50 (for the tubes and container) per blood collection device. All other costs are the same as for existing blood collection methods.

The technology

Kurin Lock (Iskus Health) is a blood collection device. The technology is self-contained and consists of:

- a blood collection tube and needle
- a flash chamber that collects, isolates and shows the first 0.15 ml of blood (flash)
- a blood collection tube that collects the remaining sample to be sent for culturing and analysis.

Innovations

The innovative aspect of the technology is that it isolates the first flash of blood from the sample. This first flash may contain contaminants (for example microorganisms from the skin surface) that could cause false-positive results during blood culture. The device does not allow backflow of blood, and does not add any extra time or work for the person collecting the blood.

Current care pathway

The standard way to collect a sample for blood culture usually involves putting a tight band (tourniquet) around the arm. The site is then cleaned with an antiseptic, for example 2% w/v chlorhexidine gluconate in 70% isopropyl alcohol. The needle is inserted, and the blood is drawn directly into blood culture bottles. Pressure is applied to the skin using a cotton wool pad and the tubes are prepared for transportation.

The following publications have been identified as relevant to this care pathway:

- NICE guideline on sepsis: recognition, diagnosis and early management
- Public Health England's UK Standards for Microbiology Investigations.

Population, setting and intended user

The technology is intended to be used for taking blood samples for culture testing. Blood culture

testing is used to confirm if there is infection when someone shows signs or symptoms of a systemic infection, for example bacteraemia, which can cause sepsis. The company estimated that more than 3 million blood culture samples are taken in the UK each year and noted that over 90% of these people are eligible for the technology.

The technology is intended for use in secondary care. The main departments that do blood culture are A&E, intensive care, acute medical and surgical wards, renal dialysis, and cancer treatment departments. The company said that it provides training for free, and that the training is simple and takes just a few minutes.

Costs

Technology costs

Kurin Lock costs £18 per unit (excluding VAT). Staff costs are the same as for existing blood collection methods.

Costs of standard care

Standard blood collection (tubes and container) costs around £1.50 per procedure.

Resource consequences

Kurin Lock is currently used in 1 NHS trust. Arrangements are being made with several trusts that want to evaluate it.

The company claims that, although Kurin Lock costs more than standard care, it has the potential to save costs.

It says that in the UK up to 10% of blood tests return false positives, leading to unnecessary treatments, time in hospital and associated costs. The company claims that using Kurin Lock can reduce these costs by reducing blood culture contamination and thus false-positive results.

A retrospective case–control study done in Northern Ireland between 2007 and 2008 found that false-positive blood culture results lead to a mean 5.4 days longer in hospital and £5,001.50 in costs (Alahmadi et al. 2011).

Dempsey et al. (2019) did a systematic review of the healthcare cost of blood culture contamination. The review included 15 published articles, dating back to 1991, that measured the

economic cost of blood culture contamination, 1 of which was from the UK. The review found that overall blood contamination rates ranged from 0.9% to 41%. Per patient, this increased:

- pharmacy charges by between $210 and $12,611
- total laboratory charges by between $2,397 and $11,152
- length of hospital stay by between 1 day and 22 days.

Another large case–control study also showed that blood culture contamination is associated with increased length of hospital stay, unnecessary exposure to antibiotics and procedures, antibiotic-associated adverse events and higher hospital charges (Davis et al. 2019).

The company says no changes are needed to facilities or infrastructure to adopt the technology.

Regulatory information

Kurin Lock is a CE marked class IIa medical device.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were identified.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Seven studies are summarised in this briefing. These include 1 before and after study,

1 retrospective and 5 prospective studies. The number of people included was not reported in any of them. Arenas et al. (2021) reported analysis of 4,030 blood samples, however, it was unclear how many of those were collected with Kurin Lock. Kastner and Beach (2019) and Ostwald and Whitsell (2021) analysed a total of 5,825 samples. Hodson et al. (2019) reported analysis of approximately 500 samples and Burnie and Vining (2021) used samples from about 250 people.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

All studies suggest that Kurin Lock can reduce the rates of false-positive blood cultures. However, the evidence was of low methodological quality. Some studies report the number of samples analysed, some report only the approximate number of samples, 1 reports the approximate number of patients, and 1 does not report either. Some of the evidence was not peer reviewed, so more high-quality research is needed comparing Kurin Lock with standard care in methodologically and statistically robust studies.

O'Sullivan and Steere (2019)

Study size, design and location

A before and after study of all patients who had blood cultures between April and June 2017 in the Hartford Hospital emergency department in the US.

Intervention and comparator

Kurin Lock and conventional blood collection.

Key outcomes

The false-positive rates for conventional blood collection taken in January, February and March 2017 were 1.4%, 1.6% and 2.1%, respectively. In April, May and June 2017, Kurin Lock was used for blood collection and false-positive rates were 0.4%, 0.5% and 0.4%, respectively. The average false-positive rate for Kurin Lock (0.44%) was significantly lower than for conventional blood collection (1.71%), an average reduction of 74.1%.

Strengths and limitations

The methods section and results section were limited. The methodology for assessing if the sample

is false positive and the patient characteristics and numbers included were not described. The study was funded by the company, but it was not involved in the study and publication.

Arenas et al. (2021)

Study size, design and location

A retrospective record review study before and after the introduction of initial-specimen diversion devices of all adult patients in the hospital emergency department who needed blood cultures for clinical suspicion of infection.

Intervention and comparator

Kurin Lock and Steripath compared with conventional blood collection.

Key outcomes

A total of 4,030 blood samples were collected and analysed between November 2017 and February 2019. The model estimated mean incidence of contaminated blood draws. For device A, there was a 95% probability that the mean rate of contamination was 45% to 86% lower than the control group. For device B, the mean rate of contamination was 53% to 87% lower.

Strengths and limitations

The study authors said that they did not endorse or oppose either device and therefore did not disclose which device was device A and device B. However, this study showed that both initial specimen diversion devices can reduce the blood culture contamination rate, leading to fewer false-positive results.

Hodson et al. (2021)

Study size, design and location

A prospective study assessing blood contamination rates over 5 months in an A&E department in the UK. The number of patients was unclear, but approximately 500 specimens were analysed.

Intervention and comparator

Kurin Lock compared with historical data on contaminated blood samples taken using conventional collection methods.

Key outcomes

After Kurin Lock was introduced, the contamination rate was calculated as less than 2%. The authors do not say what the contamination rate was before the technology was introduced, but that it consistently averaged 6% for many years. The study therefore describes an overall reduction of 66%. Two versions of the technology were used: a traditional style butterfly needle and an extension set that attaches to an intravenous cannula. The authors did not report how many of each were used. However, the results suggested no difference in the rate of false-positive results between cultures taken from a cannula and from a direct stab using a butterfly. The authors attributed this to Kurin Lock. Based on estimated costs of false-positive blood cultures, savings were estimated to be £28,000 to £72,000 for this sample.

Strengths and limitations

This study shows the clinical utility of the technology in practice. However, it was published as a non-peer-reviewed poster, so is limited in detail, and it is difficult to assess the quality and reliability of its results.

Atta and McGuire (2022)

Study size, design and location

A prospective study assessing blood contamination rates in 381 blood samples over 4 weeks from patients in an emergency department in the UK.

Intervention and comparator

Kurin Lock and standard blood collection methods.

Key outcomes

The baseline contamination rate for the emergency department was 9%. Post-intervention the authors report a decrease to 3.19%, a 65.5% reduction. The results also suggest that the reduction in contamination rates may be related to device use compliance, but this has not been statistically tested.

Strengths and limitations

The study showed a significant reduction in blood culture contamination rates with the device. The post-intervention rate of 3.19% was still above the national target of less than 3%, although the

baseline contamination rate was relatively high. The authors did not report what period the baseline contamination rate represents. There was an unexplained outlier of 0.00% contamination rate in the second week. The study is presented in poster format only so is limited in detail.

Burnie and Vining (2021)

Study size, design and location

A prospective study assessing blood contamination rates over 6 months in about 250 people in an emergency department in the US.

Intervention and comparator

Kurin Lock compared with historical data on contaminated blood samples taken using conventional collection methods, but with other contamination rate-reducing interventions in place.

Key outcomes

The average blood culture contamination rate reduced from 2.92% (2018, pre-intervention) to 1.42% post-intervention, a 51% reduction. The paper described a cost saving of $1.6 million, but it was not clear how that was estimated and if it referred to the 6-month intervention period only.

Strengths and limitations

The study authors noted that the device was not used much shortly after implementation. The primary comparator (blood culture contamination rate in 2018) was already lower than historical rates because quality improvement processes had been introduced to reduce contamination rates. Therefore, it was not possible to establish how much of the effect could be attributed to the Kurin Lock on its own. The authors did not present any measures of uncertainty around the rates.

Ostwald and Whitsell (2021)

Study size, design and location

A prospective study assessing nurse satisfaction and blood contamination rates in 1,248 blood samples from children and the cost impact of Kurin Lock in an emergency department in the US.

Intervention and comparator

Kurin Lock with staff education (n=1,177) compared with staff education only (n=71).

Key outcomes

Nurses found the device "easy to use" (45%) and "to make sense" (85%). The survey also identified that the length of tubing was "clumsy, too long, and bulky" for the paediatric patient and was "wasting too much blood". Because of these comments the device was modified mid-trial (see limitations). The authors estimated annual cost savings of $71,422 if the device was fully implemented. Contamination rates were calculated for 2 study periods. The false-positive culture rate was 10.5% in the first period and 6.06% in the second period without Kurin Lock, and 0% with Kurin Lock for both periods.

Strengths and limitations

The sample size for cultures taken without Kurin Lock was very small. The methodology of the cost analysis was not described. The study compared Kurin Lock plus staff education with staff education only, so the benefit of the technology compared with current standard care in the NHS could not be estimated. It was also not clear if staff education in the comparator arm was the same as in the intervention arm. The study authors reported that the device was updated mid-trial to address nurses' comments and to make it more suitable for paediatric use. Finally, this is a non-peer-reviewed study, which was only available on the company website. It is presented in poster format only so is limited in detail. Some of the results are in a peer-reviewed abstract in a journal supplement (Ostwald, 2021).

Kastner and Beach (2019)

Study size, design and location

A prospective study assessing blood contamination rates in 4,577 blood samples and the cost impact of Kurin Lock in an emergency department in the US.

Intervention and comparator

Kurin Lock compared with historical data on contaminated blood samples taken using conventional collection methods.

Key outcomes

The study reported that, using Kurin Lock over 3 months, 44 out of 4,577 blood cultures were contaminated, a rate of 0.96%. This compared with a historic annual rate of 2.44% (464 out of 19,017 blood cultures contaminated). Using Kurin Lock resulted in a reduction in contamination rate of 61%. The authors estimated cost savings of around $300,000 per year, based on savings of

$4,500 per contamination and minus the cost of the device.

Strengths and limitations

This was a single-centre study that showed the direct clinical and economic benefits of the technology. However, the authors noted that the contamination rate reduction was achieved not just by using Kurin Lock, but also appropriate disinfectant use, sterile techniques, a strong implementation plan and a successful change management process. Also, the methodology used to estimate the cost savings was not described. The study is presented in poster format only so is limited in detail.

Sustainability

The company claims that Kurin Lock will minimise waste and has a lower environmental impact. There is no published evidence to support these claims.

Recent and ongoing studies

No ongoing or in-development trials were identified.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three experts were familiar with this technology; 2 of them had used it.

Level of innovation

All experts agreed that the technology was novel, and 1 said that it was the first in a new class of devices. However, 2 experts also said that its safety and efficacy were uncertain.

Two experts were unaware of any competing technologies. One expert mentioned the Steripath device used in Arenas et al. (2021), 1 of the studies described in the clinical evidence section. Steripath is also used to discard the initial flash of blood, and is known and used in practice.

Potential patient impact

The experts said that Kurin Lock could reduce the unnecessary interventions that result from false-positive blood cultures such as unnecessary hospitalisation, treatments and medications.

Two experts said that Kurin Lock can be used to take all samples for blood culture from anyone who needs it, with 1 expert estimating that hundreds of thousands of people would benefit from the technology. One expert said that patients in A&E and anyone who is vulnerable, including children, older people, and people who are immunosuppressed, have cancer or renal disease or are on parenteral nutrition would particularly benefit from the technology.

Potential system impact

All experts agreed that Kurin Lock could prevent unnecessary treatment that results from false-positive results (including antibiotics), and reduce hospital stay. Two experts said that the technology could reduce long-term overall costs by reducing the costs resulting from false positives. One expert noted that the technology costs more than standard care and that a cost–benefit analysis is needed.

All experts agreed that this technology can be used in most or all district general hospitals. They said that no changes to the existing infrastructure were needed. They also said that there are no potential harms from using Kurin Lock, apart from the standard risks associated with taking a blood sample. The experts acknowledged that minimal training was needed, and that it was provided by the company.

General comments

Two experts said that Kurin Lock could replace current standard care if it reduces blood culture contaminations. One said that it could not fully replace current standard care because if blood culture is not needed then standard phlebotomy equipment is used.

None of the experts were aware of any issues with the usability of the technology. One said it was very easy to use. However, 1 expert questioned if Kurin Lock can be used to take a blood sample from central lines.

Two experts noted that issues that could prevent adoption of the technology included its cost and the need to educate staff on taking blood samples and on infection control.

The experts said that no further research is needed to address uncertainties in the evidence base although 1 suggested that the cost–benefit of Kurin Lock in the UK should be studied. One said that their study results supported the outcomes of the studies done in the US.

Expert commentators

The following clinicians contributed to this briefing:

- Andrew Barton, chair of the National Infusion and Vascular Access Society (NIVAS) and a nurse consultant for IV therapy and vascular access. Did not declare any interests.
- Bruno Coelho, senior staff nurse and clinical research nurse, emergency department, Guy's and St Thomas' NHS Foundation Trust. Did not declare any interests.
- Jane Hodson, lead IV practitioner, Guy's and St Thomas' NHS Foundation Trust. Did not declare any interests.
- Mustafa Atta, consultant microbiologist, Kings College London also commented on parts of this briefing. Did not declare any interests.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement for medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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