NICE National Institute for Health and Care Excellence

NICE guidance

Kurin Lock for blood culture collection

HealthTech guidance
Published: 3 April 2024

www.nice.org.uk/guidance/htg715

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MIB297 and MTG77.

1 Recommendations

1.1 Kurin Lock can be used in the NHS to reduce contamination in blood culture collection in emergency departments with high blood culture contamination rates while more evidence is generated.

Evidence generation

1.2 Evidence should be generated on:

- the resource impact of blood culture test results, including data on length of hospital stay, antibiotic use, further microbiological investigations and medical interventions
- staff adherence to blood culture collection methods
- baseline blood culture contamination rates, and any change in these rates from using Kurin Lock.

What this means in practice

NICE has made this recommendation because although there is uncertainty around the evidence of cost effectiveness for Kurin Lock, antimicrobial resistance is an area of high unmet need in the NHS.

Adopting Kurin Lock would need no change to standard practice. Clinical experts report that it is easy to use and needs minimal training compared with other methods to reduce contamination.

Evidence generation alongside using Kurin Lock in the NHS should give an opportunity to collect resource impact data to inform the economic modelling.

These recommendations will be reviewed within 3 years, or sooner if new evidence becomes available. Take this and the uncertainty around pricing into account when negotiating lengths of contracts.

This guidance is not accompanied by an evidence generation plan, but details of the types of evidence that should be generated are included in section 4.10.

Why the committee made these recommendations

Clinical trial evidence suggests that Kurin Lock is a safe and effective way of reducing blood culture contamination rates, compared with standard blood culture collection. It is not clear how it affects other outcomes, like length of hospital stay and antibiotic use, because the clinical trials did not formally record these outcomes.

The economic modelling is also uncertain, and it is unclear if Kurin Lock is cost incurring or cost saving. Kurin Lock costs much more than standard blood culture collection. So, it is more likely that Kurin Lock is cost saving when it is used in emergency departments with high rates of blood culture contamination. The external assessment group (EAG) estimated that if Kurin Lock reduces length of stay by only 0.5 days, and the baseline contamination rate in the department is 8%, the cost of a Kurin Lock device would need to be £10 rather than £19.50 to be cost neutral.

Evidence generation would help address uncertainties in the cost-effectiveness evidence. So, Kurin Lock is recommended for use in emergency departments with high blood culture

contamination rates while evidence is generated.

The UK Government has developed a 5-year national action plan to tackle antimicrobial resistance. This aims to contain and control antimicrobial resistance by 2040 by optimising antimicrobial use and reducing the need for and unintentional exposure to antibiotics. Kurin Lock may help to address this in emergency departments.

2 The technology

Technology

2.1 Kurin Lock (Iskus Health Ltd) is a CE-marked class IIa medical device, intended for use in collecting blood samples to check for the presence of infections. The Kurin Lock device consists of a needle, a flash chamber to collect, isolate and display the first 0.15 ml of blood drawn, and a tube to collect the remaining blood sample, which goes on to be cultured and analysed.

2.2 The company submission lists 14 different versions of the Kurin Lock device. The company stated that there is no impact on the generalisability of evidence across these various versions of the device. It advised that the different versions allow different methods of taking blood culture samples in clinical practice, such as variations in the bottles used to collect samples and taking blood samples from freshly inserted peripheral intravenous cannulas instead of through standard venepuncture.

Care pathway

2.3 People who are suspected to have a bloodstream infection or sepsis have a blood sample collected. The sample is sent to a laboratory for culturing to detect and potentially identify the infection. Current management involves cleaning the injection site with antiseptic, inserting the needle, and collecting blood directly into blood culture collection bottles. Measures such as appropriate skin and bottle preparation, taking cultures from peripheral venepuncture instead of catheters, and training, can minimise contamination risk. At least 40 ml of blood should be cultured for optimum detection of bloodstream infections. This requires at least 2 sets of blood culture samples to be taken within a few hours of each other. Kurin Lock could fit in to the pathway by replacing the standard blood culture collection device.

2.4 In clinical practice, once the infection-causing pathogen is identified, the initial

antibiotic therapy may be changed to target the identified pathogen. This allows for more appropriate and tailored treatment. If the pathogen is considered to be a contaminant, then antibiotic treatment will be stopped.

Innovative aspects

2.5 The innovative aspect of Kurin Lock is the flash chamber, which passively diverts and contains the first 0.15 ml of blood that is drawn during blood sample collection. The intended purpose of this mechanism is to isolate the blood that could contain microbes from the skin at the site of venepuncture. This is to avoid contaminating the blood sample and reduce the rate of false positive bloodstream infection results.

2.6 Blood culture contamination or false-positive blood culture results complicate interpretation and can have detrimental effects on the patient and health service. People that have increased antibiotic exposure have increased risk of potential adverse events, including allergic reactions as well as the possibility of getting other infections. This may contribute to pressures faced by secondary caused by extended hospital stays, and unnecessary testing in hospital laboratories.

Intended use

2.7 Kurin Lock is intended for use in secondary care, for people who have blood culture samples taken when bloodstream infections are suspected. This includes in emergency departments, intensive care units and other general inpatient wards. Specific subgroups who may benefit from Kurin Lock include populations in which taking blood samples may be more difficult, and so the risk of contamination is higher. For example, taking blood samples from children or from intravenous drug users. Other specific subgroups who may benefit from Kurin Lock include those in which organisms that would normally be considered contaminants may be a causative pathogen. For example, people with implanted cardiac devices or prosthetic valves.

Costs

2.8 A Kurin Lock device costs £19.50 (excluding VAT). In usual practice, 2 Kurin Lock devices will be used, so this will cost £39 per patient. All variants of Kurin Lock are the same price.

3 Evidence

NICE commissioned an external assessment group (EAG) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the project documents on the NICE website.

Clinical evidence

There are 14 publications, comprising 12 studies, that make up the clinical evidence

3.1 The evidence base consists of 12 studies reported across 14 publications with 4 full-text peer-reviewed publications, 5 abstracts and 5 posters. The EAG critically appraised the 4 full-text publications using the JBI Case Series critical appraisal checklist. The remaining 10 abstracts and posters were not formally critically appraised because of a lack of detail. The EAG considered 3 of the full-text publications to be low quality and the other study to be medium quality. For full details of the clinical evidence, see section 4 of the assessment report in the supporting documents.

It was unclear in the studies how people were selected for blood culture sampling and how contaminated cultures were identified

3.2 Most of the studies did not specify how people were selected to have blood culture collection. Only 1 of the studies described how laboratory analysis identified contaminated blood cultures (false positives). Most studies were based in the US, and there was variability in clinical practice for referrals to collect blood culture samples and laboratory analysis to identify contaminated blood cultures. So, the evidence may limit the generalisability of the study results.

Three UK NHS-based studies (not peer reviewed) reported blood culture contamination rates

3.3 There was limited published evidence on blood culture contamination rates in the NHS and the impact Kurin Lock has on this. One of these studies, based in the UK, was unpublished. The UK evidence estimated baseline contaminations of between 5% and 9%. Atta (2022) reported that the contamination rate fell from 9% to 3.1% with Kurin Lock use, while Hodson (2022) reported a statistically significant change from 6% at baseline to 1.9%. A poster presentation (Parsons, 2023) also reported that contamination fell from 5% to 2.6% after using Kurin Lock.

Other outcomes are estimated based on blood culture contamination rates, so the impact of Kurin Lock is uncertain

3.4 Length of stay was not a formal outcome in any of the included studies, but it was briefly discussed in 4 studies. Of these, Atta 2022 and Parsons 2023 were UK NHS based and 2 studies were from the US (Baxter 2020 and Burnie 2021). Both Atta 2022 and Parsons 2023 were posters that based their results on Alahmadi 2010, which investigated length of stay costs associated with false-positive blood cultures in a general hospital in Northern Ireland between July 2007 and July 2008. Kurin Lock was not used in this study, but the bed day findings were used to estimate cost savings in Atta 2022 and Parsons 2023.

3.5 Similarly, the use of antibiotic treatment was not a formal outcome in the published studies. But it was briefly referred to in 3 studies (Baxter 2020, Burnie 2021 and Ostwald 2021a/2021b). The company economic model used vancomycin treatment based on data from studies based in the US. The use of antibiotic treatment in the model was based on contaminated blood culture rates rather than the direct impact of Kurin Lock.

3.6 Staff adherence was discussed briefly in 2 studies reporting the relationship between adherence to using Kurin Lock and the blood culture contamination rate over a 4-week period. Another study reported that staff adherence ranged between 70% and 75% during a trial use of Kurin Lock.

Cost evidence

Kurin Lock is cost saving compared with standard blood culture collection in both the EAG and company models

3.7 The company submitted a decision tree comparing Kurin Lock with standard blood culture collection in an emergency department in a mixed population setting. In the model, after blood culture collection, empirical antibiotic treatment was started in a proportion of the population based on clinical suspicion of bacteraemia. A length of hospital stay was assumed for everyone who had a blood culture taken. The time horizon of the model was the length of stay in hospital, which could be up to 9 days. The decision model showed that Kurin Lock reduced contaminated blood cultures and led to a shorter length of stay, as well as reduced antibiotic treatment compared with standard blood culture collection. This resulted in a cost saving of £73 per person in the company base case and a cost saving of £8 per person in the EAG base case. The main driver for the model was the difference in length of hospital stay between Kurin Lock and standard blood culture collection, and the associated cost.

Length of stay and unnecessary antibiotic use are not formal outcomes in the evidence on Kurin Lock

3.8 Length of stay and unnecessary antibiotic use are not formal outcomes in the evidence on Kurin Lock. So, data for these parameters were taken from other sources, based on false-positive tests. The length of stay was taken from a US emergency department setting (Skoglund 2019). The length of stay for a person with a true-negative blood culture in an emergency department was 5 days. It was 7 days for people with a false-positive blood culture and 9 days for people with a true-positive blood culture. The probability of starting antibiotics and the choice of antibiotic (vancomycin) were also from this paper. The underlying bacteraemia risk was from US data and was assumed to be 7.4%.

There is some evidence of cost savings in the UK but there are limitations to this data

3.9 Atta (2022) and Parsons (2023) based their projected cost savings on the results from Alahmadi 2010, which investigated the costs associated with false-positive blood cultures in a hospital in Northern Ireland, rather than collecting resource use data during the trials. Alahmadi (2010) found there was a cost saving of about £5,000 per contaminated blood culture. The EAG considered that this result was driven by the high proportion of people in the Alahmadi study who were in an intensive care unit, where bed day costs are usually higher than in other hospital settings. This suggested that the cost savings may be overestimated in the Atta (2022) and Parsons (2023) studies. The baseline contamination rate is from Atta (2022) for the company base case. For full details of the cost evidence, see section 4 of the assessment report in the supporting documents.

The EAG changed the decision model parameters to make it more appropriate for decision making

3.10 The EAG agreed with all the clinical parameters in the company model apart from the choice of antibiotic. Clinical experts noted that in practice a wide range of antibiotics may be given. The EAG selected gentamycin for the economic analysis. The change in antibiotic in the EAG model did not have a significant impact on the cost savings of implementing Kurin Lock compared with the company model.

3.11 The most significant change to the decision model was the change of the hospital stay cost. The daily hospital costs in the company base case weighted for the population in the emergency department was £881. This uses a daily cost of a short stay from patient-level data for 1 NHS trust. The EAG considered the hospital stay costs to be high and used an alternative approach to calculate them. It applied a non-elective short-stay cost for the first day of admission. For subsequent days, it calculated excess stay costs in line with approaches used previously in NICE assessment reports. This resulted in £1,044 for the first day of admission and £377 daily for the rest of the stay, weighted for the population.

The EAG's changes to the model make Kurin Lock less cost saving

3.12 The EAG base case resulted in a cost saving of £8 per person when using Kurin Lock, whereas the company model reported a cost saving of £73. A probabilistic sensitivity analysis using a 20% variance on the EAG base case showed a 62% probability of Kurin Lock being cost saving. A one-way sensitivity analysis showed that the length and cost of stay, rate of blood culture contamination at baseline, and reduction in rate of blood culture contamination from using Kurin Lock all have the potential to make Kurin Lock cost incurring or cost neutral. The results from the sensitivity analysis indicate that at baseline contamination rates of less than 3%, there is low probability of Kurin Lock being cost saving. Contamination rates of more than 9% have a high probability of Kurin Lock being cost saving. The sensitivity analysis (see section 11 of the assessment report in the supporting documents) showed that many factors can influence the cost saving potential of Kurin Lock, and this reflects the uncertainty in the savings in different scenarios.

Using alternative PLICS data result in a lower bed day cost compared with the company model

3.13 After consultation, the EAG obtained patient level information and costing systems (PLICS) data for ICD10 codes used by the company and alternative codes for sepsis and fever from NHS Wales. The EAG considered that the ICD10 codes used by the company did not capture all the relevant population groups. The EAG presented an additional scenario using costs from the PLICS data, which were £692 per day (£549 per adult and £1,307 per person for 18s and under) and gave a base-case result of £45 per patient cost saving. At a contamination rate of 5%, 1.5 to 2 bed days would need to be saved to break even. The EAG concluded that it is difficult to estimate the most relevant cost to apply and PLICS data may be appropriate. But, caution needs to be applied to ensure that the correct patient groups are identified.

Using a 0.5 day length of stay difference in the model, Kurin lock would need to cost £10 per device to be cost neutral

3.14 The experts expressed concerns about the clinical plausibility of the difference in length of stay, so the EAG did a further 2-way sensitivity analysis. This analysis explored the cost of the device and the baseline contamination rate assuming a bed day cost based on the PLICS data. If a difference in length of stay of 0.5 days is assumed, and the baseline contamination rate is 8%, the cost of a Kurin Lock device would need to be £10 to be cost neutral.

4 Committee discussion

Clinical-effectiveness overview

The evidence suggests that Kurin Lock reduces blood culture contamination rates

4.1 All 12 studies showed a reduced blood culture contamination rate after introducing Kurin Lock. Most of the studies were based in the US but there were 3 quality improvement studies based in NHS emergency departments. Most of the studies were in adults but there was 1 study in children. Although the evidence base was limited, the committee considered it plausible that Kurin Lock would lead to the positive outcomes associated with reduced blood culture contamination.

More evidence is needed to understand the resource impact of false-positive blood culture results

4.2 There is a lack of direct evidence of the downstream resource impact of using Kurin Lock. By reducing the blood culture contamination rate, the number of false positives should also be reduced. This is expected to have an impact on a patient's length of stay and antibiotic use. The clinical experts advised that there is uncertainty in the length of stay for people who have a blood culture taken and that many factors influence this. The length of stay data used in the economic model was from Skoglund 2019, based in the US. The key parameters were that a person with a true-negative blood culture result would have a hospital stay of 5 days, and a person with a false-positive result would have a hospital stay of 7 days. The clinical experts advised that there is uncertainty in the length of stay for people who have a blood culture taken, and that many factors influence this. One clinical expert explained that other test results and clinical information are routinely used to help decide if a blood culture result is contaminated. So, in their opinion only a small proportion of people with a false-positive blood culture result would have additional treatment and a longer hospital stay. In Alahmadi (2010) a

retrospective case-control study design was used in which false-positive blood culture cases were matched with comparator cases. But the EAG and clinical experts noted that contaminated blood cultures were not all matched to comparator cases from the settings. The committee agreed that it is reasonable to assume that people in intensive care may be expected to have longer stays and higher daily stay costs compared with other settings, so the cost savings per contaminated blood culture may be overestimated. The committee agreed with the EAG's view that the Alahmadi (2010) study, which estimated longer hospital stays associated with false positives compared with Skoglund 2019, was not generalisable to a wider NHS setting because of the high proportion of people (42%) in intensive care. The committee agreed that the 2-day difference from Skoglund (2019) may not represent NHS clinical practice, and that further evidence of the resource impact in the NHS should be generated.

4.3 Further evidence is also needed on the impact of false positives on antibiotic treatment. The clinical experts advised that most people with suspected sepsis would start antibiotic treatment before the results of the blood culture test were available and so reductions in antibiotic use are difficult to estimate. The committee understood that antimicrobial resistance is an issue within the NHS. It considered that using Kurin Lock may contribute to antimicrobial stewardships efforts if people who have started antibiotics before getting their blood culture results are able to stop the antibiotics. In cases where using unnecessary antibiotics can be avoided, patient outcomes will improve, for example by reducing risk of side effects of unnecessary treatment. The committee noted that data on staff adherence to blood collection protocols is also important to determine if this reduces over time or in busy periods, and the impact on blood culture contamination rates.

Relevance to the NHS

There would be no change in practice when using Kurin Lock compared with standard blood culture collection

4.4 According to the clinical experts, Kurin Lock is easy to use and needs minimal training. The clinical experts agreed that Kurin Lock was appropriate for use in

the secondary care blood culture sampling pathway, to reduce blood culture contamination rates. It could be used to collect peripheral blood culture samples. The experts advised that Kurin Lock may improve outcomes for patients by reducing the number of repeat blood culture samples. One clinical expert stated that they had reduced contamination rates using an alternative method. This method involves staff training, ensuring samples are not taken from peripheral cannulas and introducing an additional blood bottle, which is used to isolate the first few millilitres from the blood culture sample. The expert advised that this approach reduced blood culture contamination rates, but the change in practice (one additional step) needs to be regularly reinforced and may be time-consuming. Another expert had trialled this approach before using Kurin Lock and felt that Kurin Lock is easier to adopt, and from their experience works just as well with cannulas as venepuncture.

NHS considerations overview

The cost of Kurin Lock is high compared with standard blood culture collection

4.5 The high cost of Kurin Lock compared with standard blood culture collection is a barrier to using it in the NHS, unless there is better evidence showing its impact on resources. One clinical expert commented that his hospital considered the Kurin Lock cost too high, and it has explored using an alternative approach to reduce contamination rates. The committee understood that the cost saving from the economic modelling relied on the high device cost being offset by a reduction in resource use, including hospital length of stay, associated with fewer false-positive results. Further evidence generation is needed to show that these cost savings will be realised in NHS clinical practice.

Kurin Lock is most likely to be cost saving in emergency departments with a high baseline contamination rate

4.6 The committee and clinical experts agreed that there are usually higher blood culture contamination rates in emergency departments than other hospital wards.

The EAG noted that the clinical evidence is based in emergency departments only and the economic modelling used an emergency department setting. In published literature, contamination rates of up to 9% were reported in NHS emergency departments. But clinical experts stated that it could be significantly higher. During consultation, the company stated that Kurin Lock is also likely to be cost saving in settings with a high bed-day cost, such as intensive care units. The EAG confirmed that the higher daily costs in settings such as intensive care will increase the likelihood of cost savings. Clinical experts advised that although daily costs are higher in intensive care, contamination rates are usually lower than in emergency departments. Also, length of stay in intensive care is more likely to be driven by the need for organ support. The experts also advised that while it is likely that the reduction in contamination rates seen in emergency departments are generalisable to other settings such as intensive care, the impact of the reduction in contamination rates on people in intensive care is less certain. The committee concluded that with the focus of the current evidence in emergency departments, and the associated uncertainty about the impact of Kurin Lock in intensive care units, the recommendation should only be in emergency department settings.

Cost modelling overview

The EAG's updated model is more plausible than the company's base case and most appropriate for decision making

4.7 The company's base-case model used an emergency department setting. It used a daily ward stay cost taken from patient-level data from 1 NHS trust, which was described as a non-elective short-stay cost. This was applied as a daily cost for the duration of the patient stay. The EAG did not have access to this cost data and considered the daily costs very high compared with other economic models for guidance development. The EAG used a non-elective short-stay cost as the first day of stay cost, and then calculated excess stay costs for additional days using costs from NHS Cost Collection data. The committee agreed with the changes the EAG made to the company's base-case model. It considered that the lower daily hospital stay cost used by the EAG was appropriate. After consultation the EAG obtained patient level information and costing systems

(PLICS) data from NHS Wales, which resulted in a lower stay cost compared with the company model, but was higher than the EAG model. The committee concluded that there is too much uncertainty, including around the assumption of bed days saved. Accurate information on the costing of the hospital stay and the length of stay would help reduce uncertainty in the economic modelling.

Main cost drivers

The length of stay difference and the cost associated with this affects the cost saving potential of Kurin Lock

4.8 If the difference in length of stay for people with true-negative blood culture results and false-positive blood culture results is overestimated, then the cost saving is reduced. This could lead to Kurin Lock being cost incurring rather than cost saving. The EAG confirmed that there is no length of stay difference data directly related to Kurin Lock that can be used instead of the Skoglund (2019) values to reduce the uncertainty of the model results. Because the main driver is the length of stay difference, the committee was cautious in its interpretation of the base-case results. Assuming a length of stay difference of 0.5 days, Kurin Lock would need to be £10 to achieve a break-even cost when using EAG PLICS data for bed day costs.

Cost savings

Kurin Lock is cost saving in the EAG's base case, but the sensitivity analysis indicates uncertainty

4.9 There is uncertainty about the cost effectiveness of introducing Kurin Lock, because the sensitivity analysis showed that it can be cost saving or cost incurring. Probabilistic sensitivity analysis of the EAG model reported a 62% probability that Kurin Lock would be cost saving compared with standard blood culture collection. The committee considered that the lack of evidence on the resource impact from using Kurin Lock is a significant limitation of the economic

model. Further evidence generation including information on the length of hospital stay from NHS hospitals using Kurin Lock could be used to revise the economic model.

Conclusion

Evidence generation should provide data to reduce uncertainty in the economic modelling

4.10 The key uncertainties about using Kurin Lock in the NHS are related to its cost effectiveness. Sensitivity analysis showed that Kurin Lock can be cost saving or cost incurring depending on the parameters used, particularly around the length and cost of hospital stay. The economic model in the base case assumes a 2-day difference in length of stay between people with true-negative and false-positive results, which may be overestimated. The clinical experts advised that length of stay and treatment after a blood culture test is complex and depends on many factors. The committee concluded that evidence generation alongside using Kurin Lock in the NHS would provide an opportunity to collect resource impact data that could inform economic modelling in a future review of the guidance. NICE expects to review the guidance in 3 years or sooner if evidence becomes available.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

Aamer Jawed and Amy Barr
Health technology assessment analysts

Bernice Dillon
Health technology assessment adviser

Catherine Pank
Project manager

Update information

Minor changes since publication

December 2025: Medical technologies guidance 77 has been migrated to HealthTech guidance 715. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-7573-0