NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Kurin Lock for reducing blood culture contamination

Final scope

1 Technology

1.1 Description of the technology

Kurin Lock (Kurin Inc.) is a device for collecting blood that is then cultured to check for the presence of infections. The Kurin blood culture collection set includes a vasculature connection (a butterfly needle for venepuncture or luer connection to a peripheral catheter), flexible tubing, Kurin Lock, and blood culture bottle holder. The Kurin Lock is a u-shaped chamber that collects, isolates and shows the first 0.15 ml of blood. After separating the initial blood sample, Kurin Lock automatically sends the blood through the tube into the culture collection bottle.

1.2 Relevant diseases and conditions

The Kurin Lock is intended for collecting blood samples for culture tests. Blood culture is a laboratory test to detect infections when people show signs or symptoms of a systemic infection such as sepsis.

Infections place a huge strain on the health system. Emergency departments often provide the initial management and investigations for people who present with suspected infections to hospitals. About 40% of emergency admissions are due to bacterial infections, and 33% of patients admitted to hospitals are on antibiotics at any one time. Infections also account for 66% of all hospital deaths and 50% of all bed days. In the UK, 100,000 bloodstream infections are found every year. (NHS England, 2022).

Blood culture is the primary diagnostic procedure to find bloodstream infections. It identifies the type of pathogens that cause infections and informs antimicrobial treatments. During collection, blood samples can be contaminated. Blood cultures contaminated with skin commensals or other non-pathogenic bacteria provide false positive results, resulting in people having unnecessary treatments such as antibiotics. The American Society for Microbiology (ASM) and the Clinical Laboratory Standards Institute (CLSI) recommend no more than a 2 to 3% contamination rate. In the UK blood culture contamination rates have been reported to range from 5% (Bentley et al. 2016) to 7% (Raja et al. 2009).

Blood culture contamination or false positive blood culture results complicate interpretation and can have detrimental effects on the patient and health service. For example, people may have unnecessary treatments and may have to extend their hospital stays. Additional financial burdens include laboratory testing costs on health services (Alahmadi et al. 2011).

The company notes that over 3 million blood cultures are done every year in the NHS for testing causes of blood stream infections.

1.3 Current management

The standard way to collect a blood sample for culture involves putting a tight band (tourniquet) around a person's arm. The needle injection site is cleaned with an antiseptic, for example, 2% w/v chlorhexidine gluconate in 70% isopropyl alcohol. The needle is then inserted, and the blood is drawn directly into blood culture collection bottles. At least 2 blood culture sets should be obtained within a few hours of each other to optimise the detection of pathogens. NHS England has recently published a report on improving and standardising a pre-analytical phase of the blood culture pathway across the NHS. The standardisation of practice will help reduce variations in service delivery to improve antimicrobial stewardship and patient outcomes.

UK Standards for Microbiology Investigations notes that several criteria are used when determining the clinical relevance of a positive result and when deciding whether a sample is contaminated or indeed has bacteraemia. These

include the identity of the organism, the number of positive sets, the number of positive bottles within a set, the quantity of growth, and clinical and laboratory data (including the source of culture). Some measures such as appropriate skin and bottle preparation, obtaining cultures from peripheral venepuncture instead of vascular catheters, and training can minimise the risk of contamination.

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

- NICE guideline on sepsis: recognition, diagnosis and early management
- NICE guideline on healthcare-associated infections: prevention and control in primary and community care
- NICE guideline on healthcare-associated infections: prevention and control
- ANTT clinical guideline on blood culture collection

1.4 Regulatory status

Kurin Lock is a CE marked class IIa medical device.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Improved rates of detection of people with blood stream infections (BSI)
- Reduced rates of false positive blood culture because blood samples are unlikely to be contaminated by skin organisms around injection sites
- Reduced use of unneeded antibiotic treatment
- Reduced unnecessary further interventions such as laboratory tests to rule out suspected bacteraemia
- Avoiding treatment delays
- Reduced length of hospital stay

The benefits to the healthcare system claimed by the company are:

- Reduced blood culture contamination rates

- Improved patient management using appropriate use of antibiotics
- Improved efficiency in the use of resources such as staff and laboratory tests
- Reduced risk of hospital-acquired infections and associated costs and resource use associated with management.

2 Decision problem

Population	People who need a blood culture test within a secondary care setting
Subgroups	• People who present with signs or symptoms of infection • People at increased risk of infections such as those who are immunocompromised • People in whom sampling blood can be challenging for example intravenous drug users or children
Intervention	Kurin blood culture collection including Kurin Lock
Comparator(s)	Standard blood culture collection (tubes and container)
Outcomes	The outcome measures to consider include: • Blood culture contamination rate • Positive and negative predictive values • Rates of antimicrobial prescriptions • Use of unneeded antibiotic treatment • Unnecessary further interventions such as laboratory tests to rule out suspected bacteraemia • Treatment delays • Length of hospital stay • Rates of hospital acquired infection • Patient-reported outcome measures such as health related quality of life • Patient-reported experience measures • Device-related adverse events.
Economic analysis	A health economic decision model will be developed comprising a cost-comparison analysis. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity analysis and appropriate scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on the cost-comparison estimates.
.Other considerations	No

Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic? No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality? No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance? No
Any other special considerations	Not applicable

3 Stakeholders

3.1 Healthcare professional organisations

The following healthcare professional organisations have been invited to register as stakeholders for this guidance development:

- Association for Clinical Biochemistry and Laboratory Medicine
- Academy of Medical Sciences
- The Association of Clinical Microbiologists and Biochemists (ACMB)
- Academy of Medical Royal Colleges
- Association for Paediatric Emergency Medicine
- Association of Clinical Pathologists
- Association of Clinical Scientists
- British Association of Emergency Medicine
- British infection association
- British Trauma Society
- British Association of Critical Care Nurses
- Healthcare Infection Society
- Infection Prevention Society
- Institute of Biomedical Science
- Intensive care society
- Neuro-Anaesthesia and Critical Care Society of Great Britain and Ireland
- NHS Blood and Transplant

- Paediatric Intensive Care Society
- Royal College of Emergency Medicine
- Royal College of General Practitioners
- Royal College of Nursing
- Royal Society for Public Health (RSPH)
- Society for Acute Medicine
- Society for General Microbiology
- The UK sepsis trust

3.2 Patient and carer organisations

NICE's Public Involvement Programme contacted the following patient and carer organisations and invited them to register as stakeholders for this guidance development:

- Action Cancer - NI
- African Caribbean Leukaemia Trust (ACLT)
- Anthony Nolan
- Blood Cancer UK
- BME cancer communities
- Cancer Black Care
- Cancer Research UK
- Cancer Support UK
- Cancer52
- Children's Cancer and Leukaemia Group
- Chronic Lymphocytic Leukaemia Support Association (CLLSA)
- Chronic Myeloid Leukaemia Support Group (CML Support)
- Critical Care Patient Liaison Committee
- Diabetes Research & Wellness Foundation
- Diabetes UK
- DKMS
- DWIB Leukaemia Trust
- Follicular Lymphoma Foundation
- Foot in Diabetes UK (FDUK)

- Friends of the Cancer Centre (NI)
- Helen Rollason Cancer Charity
- ICU Steps
- Independent Cancer Patients' Voice
- InDependent Diabetes Trust
- Juvenile Diabetes Research Foundation (JDRF)
- Leukaemia Cancer Society
- Leukaemia Care
- Leukaemia UK
- Lymphoedema support network
- Lymphoma Action
- Macmillan Cancer Support
- Maggie's Centres
- MDS UK Patient Support Group
- MPN Voice
- Myeloma UK
- Penny Brohn Cancer Care
- Pernicious Anaemia Society (PAS)
- Primary Sclerosing Cholangitis Support (PSC Support)
- Sickle Cell Society
- The Aplastic Anaemia Trust (AAT)
- The Haemophilia Society
- The ITP Support Association
- The Rik Basra Leukaemia Campaign
- Trauma Care
- Tenovus Cancer Care
- UK Thalassaemia Society
- WMUK
- World Cancer Research Fund (WCRF UK)
- XLH UK