Horizon scan for new and innovative diagnostics for antimicrobial resistance in surgical site infections

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Conflicts of Interest

The authors declare no conflicts of interest.

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Contents

How to Cite This Document 2
Acknowledgements and Disclaimers 2
Conflicts of Interest 2
Key Findings 5
Abstract 6
Background 8
Aim 9
Method 9
- Scope 9
- Eligibility criteria 10
- Search Strategy 10
- Screening and Data Collection 10
- Data Extraction 11
- Data Analysis 13

Results 14
- Overview of SSI Diagnostic Technologies 16
  - PCR and Sequencing Technologies (n=11) 16
  - Analytical Assays (n=17) 16
  - Biosensors (n=3) 16
  - Other Diagnostic Techniques (n=3) 17
- Diagnostic Targets 17
- Technology Readiness Levels (TRLs) 20
- Regulatory status 22
- Turnaround Time 22
- Developer Location 23
- Sample Types 24
- Diagnostic Accuracy 24
- Conditions 26
- Populations 26

Discussion 26
Implications and Recommendations 28
Conclusion 28
Appendix A 30

Bibliographic database searches **30**
Embase (Ovid) 30
IEEE Xplore 33
Cochrane CENTRAL 33
Clinical Trials **35**
US Clinical Trial Register 35
WHO clinical trial registry 35
Appendix B **36**
References **38**

Key Findings

- **Technologies identified**: 34 SSI diagnostic technologies, including PCR/sequencing (n=11), analytical assays (n=17), biosensors (n=3), and other methods (n=3).
- **Global AMR priorities**: Many of the technologies identified target organisms included in the WHO priority pathogen list, particularly Pseudomonas aeruginosa, Klebsiella pneumoniae, and methicillin-resistant Staphylococcus aureus (MRSA).
- **Diagnostic accuracy**: PCR and sequencing platforms demonstrated the highest sensitivity and specificity, some approaching 100%. Analytical assays and other methods showed variable performance.
- **AMR detection**: Only nine technologies reported specific detection of antimicrobial-resistant strains.
- **Technology readiness**: Majority of emerging technologies were at TRL 6 (n=16), while eight technologies were at TRL 9, and nine were at early-stage TRL 3–5.
- **Regulatory status**: Only one technology, Xpert® MRSA/SA SSTI, had received regulatory approval from the U.S. Food and Drug Administration (FDA).
- **Turnaround time**: Data were reported for 10 technologies, ranging from 18 minutes to seven days, highlighting limited operational data.
- **Developer location**: Most technologies were developed in USA (n=9), Japan (n=4), Germany (n=4), and China (n=4). Two technologies were developed in the UK. Other countries were represented by single innovations.
- **Sample types**: Blood (n=8) and swab samples (n=5) were the most commonly used. A subset of technologies (n=4) used multiple sample types, including combinations such as tissue and blood; explants, synovium, and tissue; various types of tissue samples, and blood with surgical discard tissue.
- **Implications**: Emerging technologies hold promise for improved SSI diagnosis and AMR detection, but gaps in clinical validation, operational feasibility, and standardised reporting limit their current applicability.

Abstract

Introduction

Surgical site infections (SSIs) contribute significantly to postoperative morbidity and antimicrobial resistance (AMR), highlighting the need for early and accurate diagnosis to improve outcomes and guide appropriate antimicrobial use. This horizon scan aimed to identify and characterise emerging diagnostic technologies for SSIs, with a focus on AMR detection, technology readiness, and operational feasibility.

Method

A comprehensive search was conducted across bibliographic databases, clinical trial registries, regulatory sources, and grey literature to identify diagnostic technologies at all stages of development. Inclusion criteria were defined using the PICOS framework, targeting technologies for SSI detection with potential AMR relevance. Data were extracted on technology name, test description, developer name, diagnostic target, AMR detection, population, turnaround time, sample type, and diagnostic accuracy. Technology readiness levels (TRLs) were assigned based on available descriptions.

Results

A total of 34 diagnostic technologies met the inclusion criteria, categorised into PCR and sequencing (n=11), analytical assays (n=17), biosensors (n=3), and other diagnostic approaches (n=3). PCR and sequencing-based technologies demonstrated the highest diagnostic accuracy, with several platforms achieving sensitivities and specificities approaching 100%. Most innovations were at TRL 6 (n=16), reflecting systems or prototypes demonstrated in relevant clinical or laboratory environments. Established methods, including PCR and disc diffusion, were at TRL 9 (n=8). Turnaround times were inconsistently reported, ranging from 18 minutes to 7 days, limiting assessment of operational feasibility. Technologies were primarily developed in the USA, Japan, Germany, and China. Only nine technologies reported detection of AMR strains. Many of the technologies identified focus on organisms included in the WHO priority pathogen list, particularly Pseudomonas aeruginosa, Klebsiella pneumoniae, Enterobacter spp., and methicillin-resistant Staphylococcus aureus (MRSA).

Conclusion

The SSI diagnostic landscape is diverse, with established molecular diagnostics coexisting alongside emerging innovations such as biosensors. While many show promise, further validation and operational evaluation are needed. Barriers such as infrastructure demands and shortages of skilled personnel present significant challenges to operationalising these technologies in low-resource settings. Addressing these constraints will be essential to ensure equitable access and global impact. Greater standardisation in reporting, clinical validation, and consideration of regulatory and implementation pathways is needed to translate these innovations into routine surgical care and support efforts to combat AMR. Notably, many of

the identified technologies target WHO priority pathogens, demonstrating alignment with global AMR priorities.

Background

Antimicrobial resistance (AMR) poses a critical global health threat, contributing to approximately 700,000 deaths annually due to drug-resistant infections.[1] Without effective antimicrobials, common infections may become untreatable, leading to widespread illness and death.[2] By 2050, AMR is projected to cause up to 10 million deaths annually. Economically, the global loss in productivity due to AMR could reach an estimated 100 trillion United States dollars, with both direct and indirect effects hitting low- and middle-income countries particularly hard.[3]

Surgical site infections (SSIs) are infections that develop within 30 days of a surgical procedure (or up to one year after surgery in patients receiving implants) and affect either the incision or deep tissue at the surgical site.[4] SSIs develop when bacteria enter through surgical wounds, often delaying healing.[4,5] SSIs are generally classified into three categories: (1) superficial incisional SSIs, affecting only the skin and subcutaneous tissue, often presenting with signs of inflammation; (2) deep incisional SSIs, involving deeper soft tissues and potentially identified up to one-year post-operation if an implant is involved; and (3) organ/space SSIs, involving internal organs or anatomical spaces beyond the incision site.[6]

SSIs account for approximately 15% of all hospital-acquired infections and are linked to longer hospital stays and increased costs due to extended antibiotic treatment.[7] The microbiology of SSIs includes both bacteria (Gram-negative and Gram-positive bacteria), and fungi, with a shift over time from normal flora to antimicrobial-resistant pathogens.[8] Emerging antimicrobial-resistant pathogens include *Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacter* spp., all of which are highly adaptable and capable of causing life-threatening infections.[8] Recognising their clinical importance, the World Health Organisation (WHO) has prioritised several as urgent targets for research and development. Carbapenem-resistant *A. baumannii* and *P. aeruginosa*, and third-generation cephalosporin-resistant *K. pneumoniae* and *Enterobacter* spp. are listed as "critical" priority pathogens, while vancomycin-resistant *E. faecium* and Methicillin-Resistant *Staphylococcus aureus* (MRSA) are classified as high-priority threats.[8]

SSIs pose significant challenges in healthcare, affecting millions of patients annually and contributing to AMR.[9] Early and accurate diagnosis of SSIs is essential to reduce morbidity, mortality, and the burden on healthcare systems.[10] Conventional diagnostic approaches for SSIs primarily rely on symptoms, blood tests, microbiological cultures, and imaging, but these often lack precision due to slow culture times, difficulty growing certain organisms, and pathogen diversity, resulting in delayed or missed diagnoses.[10,11] In recent years, diagnostic technologies have advanced significantly, moving from empirical assessments to precision-based methods driven by molecular biology, genomics, and advanced imaging.[11] Polymerase chain reaction (PCR) technologies, such as real-time quantitative PCR (qPCR), multiplex PCR, and digital PCR, now provide faster and more accurate results, with qPCR delivering nucleic

acid analysis within hours compared to the 24–48 hours required for cultures.[11] Similarly, metagenomic next-generation sequencing enables unbiased detection of all microbial DNA in a sample, overcoming the limitations of traditional culture methods. These innovations improve sensitivity, accuracy, and speed, supporting earlier pathogen identification, more targeted treatment, and better antimicrobial stewardship.[11]

Aim

This report provides an in-depth analysis of new and emerging diagnostic tests for SSIs, with a particular emphasis on enhancing early detection and identifying AMR. We present a comprehensive overview of findings from our research, including the criteria used for data collection, an assessment of the technology readiness levels, and description of the identified diagnostic technologies. This horizon scan serves as an update to the previous scan conducted in 2022.

This project has been commissioned by the Horizon Scanning, Demand Signalling and Business Development team in the NHSE Innovation Research and Life Science Strategy Group to support the NHSE Antimicrobial Resistance Diagnostics Programme. This work directly supports the objectives of the UK's National Action Plan for Antimicrobial Resistance 2024–2029, published in May 2024, by highlighting technologies that can facilitate more targeted treatment, minimise inappropriate antimicrobial use, and help combat the spread of antimicrobial resistance.

Method

Scope

The scope of this horizon scan encompassed diagnostic technologies for the identification of SSI and detection of AMR, across all stages of development, from initial concept to readiness for clinical implementation.

The data source comprised:

- Clinical trial registries (ClinicalTrials.gov, WHO International Clinical Trials Registry Platform [ICTRP])
- Bibliographic databases (Embase OVID, IEEE Xplore, CENTRAL)
- US FDA 510(k) Premarket notification database
- Device classification under Section 513(f)(2) (De Novo) database
- Devices@FDA database
- National Institute for Health and Care Excellence (NICE) health technology appraisals

- National Institute for Health and Care Research (NIHR) Health Technology Assessment database
- International Network of Agencies for Health Technology Assessment (INAHTA) database

Eligibility criteria

The inclusion criteria were defined using the PICOS framework:

- **Population:** any (children and adults)
- **Intervention:** Any diagnostic technology aimed at identifying SSIs and either directly associated with the detection of AMR or had the potential to be used for this purpose
- **Comparator:** Other laboratory diagnostic testing or none
- **Outcomes:** Overview of the technology, including diagnostic accuracy, intended setting, treatment pathway (e.g. detection, monitoring, diagnosis). Where reported, information on developmental status and cost-effectiveness was also captured
- **Setting:** All stages of the care pathway were considered, with likely care settings such as inpatient wards, outpatient clinics/community care, General Practice (GP clinics), or specialist infectious disease or surgical clinics.

Studies that did not address SSI detection or were not relevant to AMR detection or applicability were excluded.

Search Strategy

Our searches covered the bibliographic and non-bibliographic sources within scope, using a combination of keywords and search terms related to diagnostics, AMR, and SSIs. A prototype search was developed in Embase (Ovid) and translated to other bibliographic databases (full search strategies are provided in Appendix A). Non-bibliographic database searches used a pragmatic approach, focusing on AMR and SSI concepts depending on the source. A detailed description of the sources searched, and the strategy used is available in Appendix A. One limitation of the search strategy was the restriction to English-language publications and sources, which may have introduced geographic bias and potentially overlooked relevant innovations reported in non-English-speaking regions.

Screening and Data Collection

Following completion of the systematic searches on the clinical trial registries and other databases, all results were de-duplicated using EndNote. The studies were then screened using

Rayyan[12], an online screening tool. Initially, four reviewers independently and blindly screened 20% of the studies to establish a baseline and ensure consistency, assessing titles and abstracts against the predefined eligibility criteria. Once consensus was reached on this initial set, the remaining studies were screened individually. In the second phase, full-text articles were obtained and screened for inclusion. At any stage involving single screening, uncertainties or queries were discussed with another team member or the project lead to reach consensus on inclusion or exclusion.

Grey literature was exported and collated in Microsoft Excel, de-duplicated, and manually screened against the eligibility criteria by two reviewers. Each study was classified as either 'include' or 'exclude,' with any uncertainties flagged for discussion and resolved through consensus. Quality assurance checks were performed by the project lead to confirm accuracy, completeness, and alignment with the predefined criteria. This process helped minimise selection bias and maintain rigour in the inclusion of non-bibliographic sources.

All included studies were sent to NHS E for clinical adjudication. This was a quality assurance step to ensure the included studies matched what was expected. Further exclusions were made at this stage.

Data Extraction

Manual data extraction for each of the included studies was independently conducted by one reviewer. For 20% of studies, one reviewer completed data extraction, and another checked for accuracy. The remaining 80% of studies were allocated to individual members of the review team. Data were extracted onto an Excel data extraction form. Any queries relating to the data extraction were resolved through discussion amongst the review team. After all data extraction was completed, a random 20% check was conducted by another reviewer to ensure accuracy and consistency. Quality assurance checks were also performed by the project lead to confirm accuracy of extracted data.

The following data fields were extracted from each of the included studies:

- Record overview
  - Study URL
  - Condition
  - Broad condition category

- Product information
  - TRL
  - Product/test name
  - Developer name
  - Developer location
  - Cost (if available)
  - Test description
  - AI element

  - Turnaround time
  - Regulatory status
  - Trial ID

- Device Target
  - Parameter measured
  - Biomarkers
  - Gram-negative bacteria
  - Gram-positive bacteria
  - Fungi
  - Other targets
  - AMR genes

- Product application
  - AMR detection
  - Pathogen or Antimicrobial susceptibility
  - Population
  - Comorbidity
  - Purpose
  - Operator
  - Settling
  - Sample type

- Diagnostic accuracy
  - Sensitivity
  - Specificity
  - Area under the curve (AUC)
  - Positive predictive value (PPV)
  - Negative predictive value (NPV)
  - Likelihood ratios

Technology readiness levels (TRLs) were not explicitly reported in the included studies but were instead assigned by reviewers based on the descriptions and information available in the source material. To ensure consistency and accuracy, quality assurance checks were conducted by a second reviewer. TRLs are a standardised system used to evaluate the maturity and development stage of new technologies (Table 1). The scale ranges from TRL 1, which represents the initial stage where a basic concept is established with a well-defined theoretical basis, to TRL 9, which indicates the highest level of readiness, that is, where the technology has received regulatory approval or notification and is commercially available.[13]

Technology readiness levels (TRLs)	**TRL 1:** Preliminary idea with well characterised theoretical case **TRL 2:** Principles are demonstrated through experimentation **TRL 3:** Early proof of concept demonstrated in the laboratory **TRL 4:** Late proof of concept demonstrated in real life conditions **TRL 5:** Technology refined and ready for initial human trials **TRL 6:** Technology has completed initial trials and demonstrates preliminary safety data **TRL 7:** Technology completes secondary trials and demonstrates further evidence for safety and efficacy **TRL 8**: Technology completes late-stage trials and has all evidence required to prove safety and efficacy **TRL 9:** Regulatory approval/notification takes place, product is made available to the market

Table 1. Table outlining technology readiness level assessments

Relevant information for each data field was captured wherever available to ensure a consistent and comprehensive dataset. When specific details were missing or not disclosed in the source material, “Not reported” was recorded. This method helped maintain transparency in the data extraction process.

Data Analysis

Subgroup analysis was performed to categorise the technologies into four groups, namely PCR and sequencing technologies, analytical assays, biosensors, and other diagnostic techniques. Trends were identified through descriptive synthesis of the extracted data, examining parameters such as TRLs, turnaround times, sample types, diagnostic accuracy metrics, and the ability to detect pathogens and/or antimicrobial susceptibility. This approach allowed the identification of developmental stages, practical applications, and diagnostic performance, providing a structured overview of the innovation landscape.

Results

Our horizon scan identified a total of 791 studies from bibliographic databases and registries, and 484 studies from websites and regulatory databases. Following de-duplication, screening of titles, abstracts and full text, and exclusion of ineligible studies, a total of 34 studies, describing 34 unique technologies, met the predefined inclusion criteria and were eligible for data extraction. The included technologies are presented in Appendix B. Figure 1 illustrates the flow diagram outlining the process of record identification, screening, and selection for inclusion.

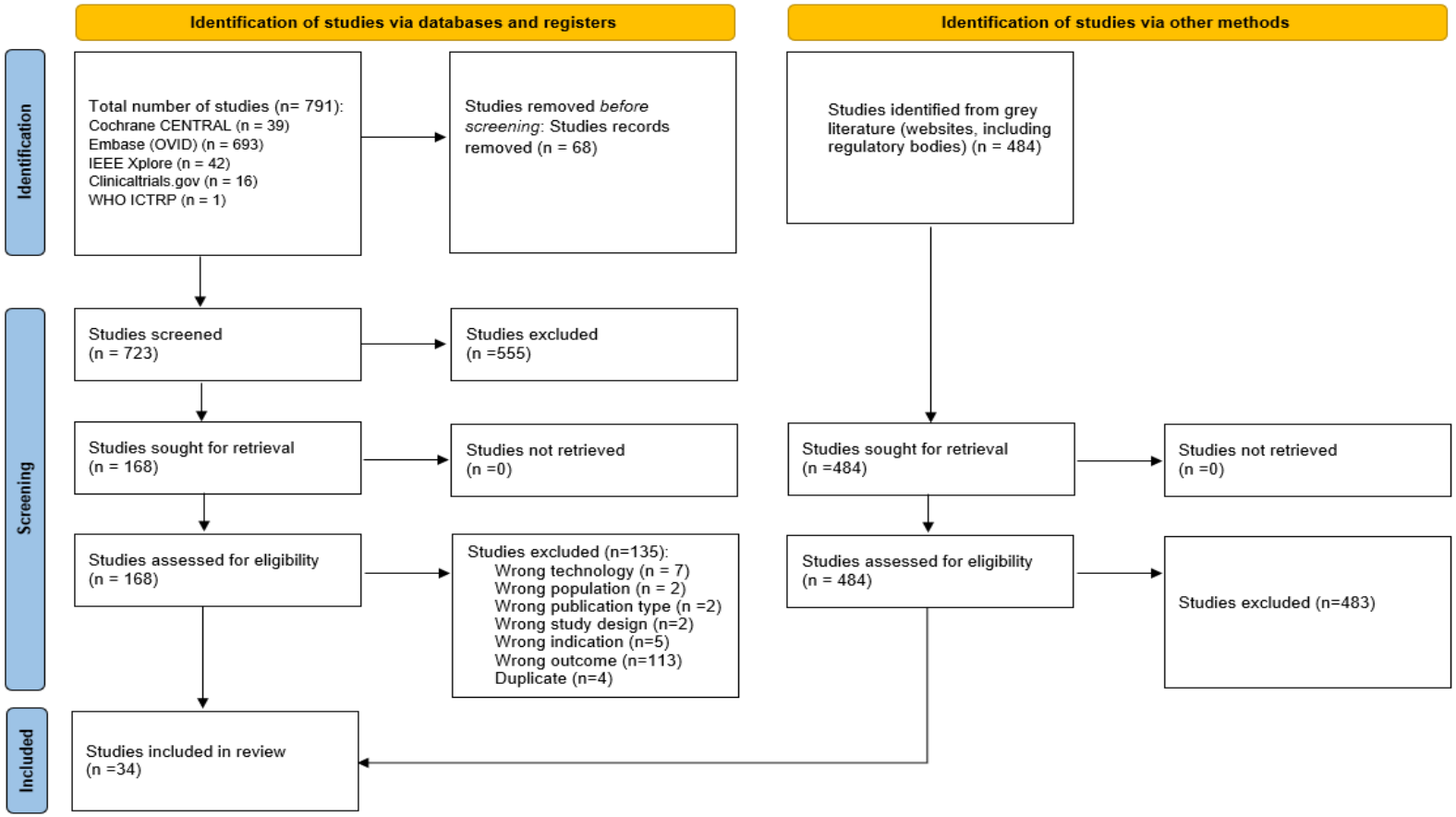

Figure 1. Flow diagram showing the final number of included technologies

Overview of SSI Diagnostic Technologies

A total of 34 diagnostic technologies were identified through the SSI horizon scan (see Appendix B). These were broadly categorised into four main groups: PCR and sequencing technologies, analytical assays, biosensors, and other diagnostic techniques. Where possible, technologies were also characterised by their application, and whether they included detection of AMR. Each category offers distinct advantages and faces unique limitations in the context of SSI diagnostics.

PCR and Sequencing Technologies (n=11)

This group includes polymerase chain reaction (PCR) (n=4), next-generation sequencing (NGS) (n=3), PCR combined with ribosomal ribonucleic acid (rRNA) sequencing (n=2), metagenomic NGS (mNGS, n=1), and nanopore sequencing (n=1). These technologies are highly sensitive and specific, capable of detecting a wide range of pathogens and, in some cases, AMR genes. They were applied to detect infections following diverse surgical procedures, including general, spinal, liver, dermatology, and abdominal surgeries. Seven of these technologies incorporated AMR detection alongside their primary infectious targets, enhancing their clinical utility by enabling simultaneous identification of pathogens and their resistance profiles, which supports more targeted antimicrobial therapy. However, these methods can be resource-intensive, costly, and may require specialised laboratory infrastructure, which may limit widespread adoption.

Analytical Assays (n=17)

This group comprises immunoassays (n=9), mass spectrometry-based tests (n=2), and other assays not otherwise classified (n=6). Analytical assays are versatile, often faster and easier to implement than sequencing methods, and can provide insights into host-response biomarkers. They were applied across a wide range of surgical contexts, including orthopaedic, spinal, liver, gastrointestinal, and obstetric procedures. Only one test – Matrix-Assisted Laser Desorption Ionization-Time of Flight (MALDI-TOF) mass spectrometry – incorporated AMR detection. While analytical assays enable rapid and high-throughput screening, their diagnostic accuracy can vary, particularly when relying on single biomarkers, and they may require further validation in clinical settings.

Biosensors (n=3)

Biosensors are designed to detect infections in real time, with potential for point-of-care application. They were primarily evaluated for infections following gastrointestinal surgery (n=2) and orthopaedic surgery (n=1). Biosensors are generally rapid and minimally invasive, offering potential for bedside monitoring. However, none of the identified biosensor

technologies included AMR detection, and most remain at mid-level development stages (4-6), with limited clinical validation data.

Other Diagnostic Techniques (n=3)

Three technologies did not align with the categories above and were grouped as other diagnostic approaches. This group includes disc diffusion method, PET imaging, and haematology analyser. These technologies were applied in general surgery (n=2) and transplant surgery (n=1), with disc diffusion method incorporating AMR detection. They offer alternative approaches when molecular or immunoassay methods are unsuitable, and some are well-established in clinical practice. Limitations include slower turnaround times (for example, disc diffusion, turnaround time >16 hours), lower sensitivity compared to molecular methods, or the need for specialised imaging infrastructure.

Diagnostic Targets

The diagnostic targets varied depending on whether the test focused on biomarker measurement or pathogen detection. Of the identified technologies, seventeen technologies targeted biomarkers, sixteen focused on specific pathogens, and one study measured physiological parameters such as oxygen saturation and temperature.

A total of 26 biomarkers were reported for potential SSI detection. The most frequently studied were C-reactive protein (CRP, n=4) and interleukin-6 (IL-6, n=4). Additional biomarkers included procalcitonin (PCT, n=3), tumour necrosis factor-alpha (TNFα, n=2), white blood cell count (n=2), and presepsin (n=2). Collectively, these biomarkers reflect a broad search for reliable host-response indicators of SSI, although consistency across studies was limited.

Most pathogen-targeting technologies demonstrated broad-spectrum detection, identifying multiple species or genera, with one platform capable of identifying up to 150 genera (Table 2). Others were designed for targeted detection of clinically significant pathogens, including methicillin-resistant Staphylococcus aureus (MRSA) and Pseudomonas aeruginosa. Among the 16 technologies identifying pathogens, nine also reported the ability to detect antimicrobial-resistant (AMR) strains (Table 2). The most commonly reported target pathogen was S. aureus (n=6), followed by E. coli (n=5) and P. aeruginosa (n=5), and Klebsiella species (n=4). Across the pathogen-targeting technologies identified, the majority focus on organisms included in the WHO priority pathogen list, notably P. aeruginosa, Klebsiella pneumoniae, Enterobacter spp., and methicillin-resistant Staphylococcus aureus (MRSA). Technologies such as 16S rRNA sequencing, the Kirby Bauer disc diffusion method, nanopore sequencing, and metagenomic next-generation sequencing (mNGS) are used to identify critical-priority pathogens. In parallel, technologies including Xpert MRSA/SA SSTI, PCR, and MALDI-TOF mass spectrometry focus on high-priority pathogens (Table 2). Overall, the diagnostic landscape demonstrates substantial alignment with WHO research and development priorities, particularly through technologies enabling rapid identification of resistant gram-negative pathogens and MRSA.

Product / Test name	Developer name	Target pathogens	AMR detection	WHO pathogen priority category	TRL
16S rRNA sequencing	Department of Plant Biology and Biotechnology, University of Benin, Ugbowo, Benin City, Nigeria	Pseudomonas aeruginosa	Yes	Critical	9
Kirby Bauer disc diffusion method	National Institute for Biotechnology and Genetic Engineering College, Pakistan	Pseudomonas aeruginosa	Yes	Critical	9
Xpert® MRSA/SA SSTI	Cepheid	Staphylococcus aureus (SA) and methicillin-resistant Staphylococcus aureus (MRSA)	Yes	High (MRSA)	9
PCR	Sohag University	MRSA	Yes	High	6
Unyvero IAI test	Curetis	Gram negative bacilli, Gram positive bacteria, anaerobic bacteria, and fungi, including antibiotic resistance genes such as certain ESBL (CTX-M) and carbapenemases.	Yes	None	6
Nanopore Sequencing	Division of Surgical Research, Department of Surgery, Mayo Clinic, Rochester, Minnesota, USA	Enterococcus, Klebsiella, and Streptococcus species; Citrobacter freundii, Escherichia coli, E. cloacae, Fusobacterium nucleatum, and Veillonella	Yes	Critical (Klebsiella spp.)	6

		spp.; AMR phenotypes			
Metagenomic Next-generation Sequencing	Division of Infectious Diseases, Department of Internal Medicine, Taichung Veterans General Hospital, Taichung, Taiwan, R.O.C.;	Streptococcus spp., Staphylococcus spp., other gram-positive bacteria, Enterobacter spp., Enterococcus spp., Citrobacter spp., Pseudomonas aeruginosa, Bacteroides fragilis, Escherichia coli, Klebsiella pneumoniae, other gram-negative bacteria	Yes	Critical (P. aeruginosa, Klebsiella pneumoniae, Enterobacter spp.)	6
Matrix-Assisted Laser Desorption Ionization-Time of Flight (MALDI-TOF) mass spectrometry, MiSeq V3 chemistry (whole genome sequencing)	Brucker daltonics/Illumina/Université Catholique de Louvain UCLouvain	Staphylococcus aureus, Enterobacterales, E. coli	Yes	High (S. aureus)	6
Multiplex PCR method	Tokyo University of Pharmacy and Life Sciences	Cutibacterium acnes, Cutibacterium avidum, and Cutibacterium granulosum	Yes	None	4
Next generation sequencing	Northern Louisiana Men's Health Fellowship-Willis Knighton Health System	E. coli, Klebsiella pneumonia, pseudomonas aeruginosa	No	Critical (P. aeruginosa, Klebsiella pneumoniae)	9
Smear test and PCR	Clinic, Neurosurgical, University of Munich (LMU), Campus Grosshadern, Marchioninistrasse 15, 81377,	Staphylococcus aureus and Cutibacterium acnes	No	High (S. aureus)	6

	Munich, Germany				
Medium enriched for newly synthesized antibodies (MENSA)	University of Colorado, (USA)	S. aureus	No	High	6
MALDI Biotyper system with pretreatment membrane filtration (BACpro®)	Department of Biochemistry, School of Life and Environmental Science, Azabu University, Kanagawa, Japan	E. coli and E. faecalis	No	None	6
PET radiotracer	University of Nottingham	S. aureus and P. aeruginosa	No	Critical (P. aeruginosa), High (S. aureus)	6
16s rRNA Next Generation Sequencing	Hannover Medical School	Detected over 150 different genera. e.g. Enterococcus, Streptococcus, Escherichia/Shigella, and Klebsiella	No	Critical (Klebsiella spp.), High (Enterococcus spp.)	5
Fluorescent-conjugated antibodies	Rhode Island Hospital	Gram-positive bacteria and gram-negative bacteria	No	None	4

Table 2. SSI diagnostic technologies for pathogen identification, including those reporting detection of AMR strains.

Technology Readiness Levels (TRLs)

The current diagnostic landscape for SSIs encompasses technologies at a wide range of maturity levels (Figure 2). Conventional microbiological methods, such as disc diffusion, assays, and standard PCR platforms, are already in routine clinical use and therefore classified at TRL 9 (n=8), representing proven systems that are fully deployed in operational healthcare environments. Notably, no technologies were identified at TRL 8, and only one technology was assigned TRL 7.

The majority of emerging innovation is concentrated around TRL 6, representing systems or prototypes that have been demonstrated in relevant clinical or laboratory environments but have not yet progressed to large-scale validation or widespread adoption. A total of 16 technologies were identified at this level, including advanced molecular approaches such as nanopore sequencing and mNGS, as well as immunoassays targeting specific biomarkers,

biosensor platforms, and early-stage digital monitoring devices designed for SSI detection. These technologies have typically undergone proof-of-concept studies or small-scale clinical validation; however, additional evidence is needed to confirm their performance, reproducibility, and cost-effectiveness in real-world clinical settings.

At earlier stages, corresponding to TRL 3–5, a total of 9 technologies were identified, representing exploratory assays and platforms under development. These included fluorescent antibody probes, breath-based diagnostic approaches, cytokine and immune marker panels, and novel biosensors. While these approaches show considerable potential to enhance SSI detection, they remain largely experimental, with limited clinical data available. Further analytical validation, optimisation, and early-stage clinical studies are needed before these technologies can progress to higher TRLs and demonstrate feasibility for routine surgical practice.

Taken together, the TRL distribution highlights a field where established microbiological diagnostics continue to dominate clinical practice, but a substantial wave of innovation is advancing through mid-level development.

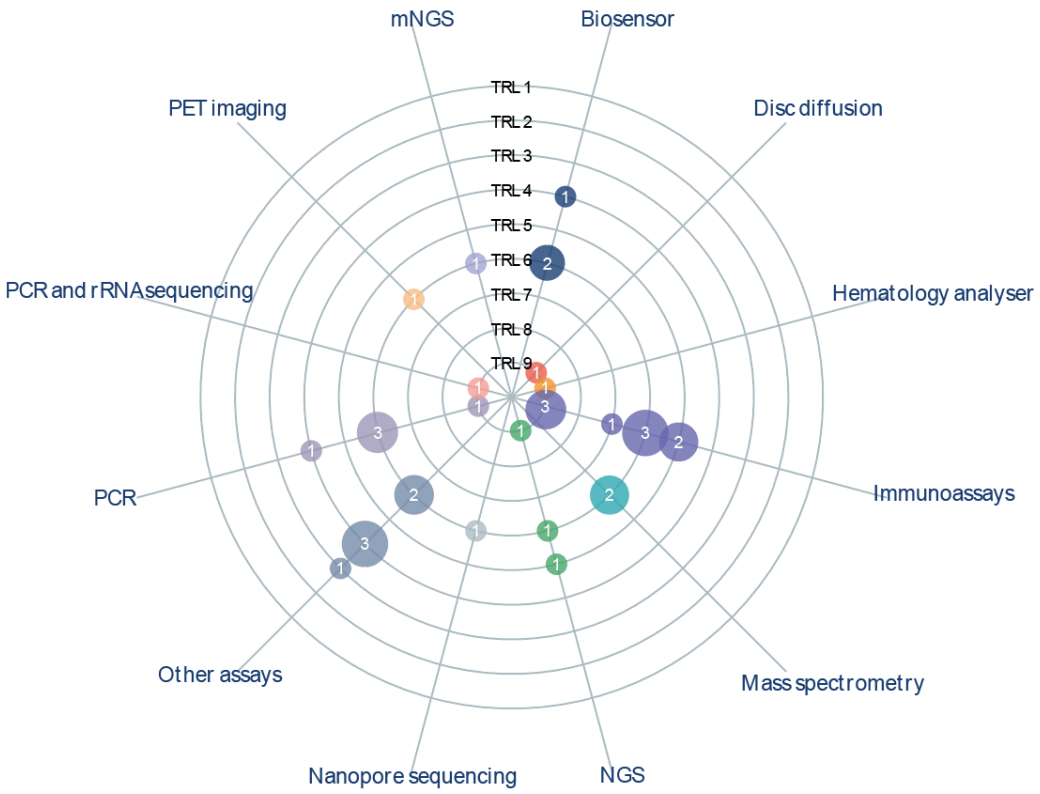

Figure 2. Technology radar chart displaying all identified technologies across TRLs and broad categories

Regulatory status

Of the 34 technologies identified in the scan, eight were assigned a TRL of 9, indicating they are fully developed and potentially ready for market deployment. However, only one of these technologies, Xpert® MRSA/SA SSTI, had received regulatory approval from the U.S. Food and Drug Administration (FDA). The absence of approval for most technologies suggests that many SSI diagnostics remain at the pre-commercial or validation stage.

Turnaround Time

Most of the technologies identified in this horizon scan did not report a turnaround time, with 24 out of 34 technologies lacking this information. Among the 10 technologies that did report turnaround times, there was considerable variability, ranging from 18 minutes to 7 days (Table 3). These findings highlight an important gap in the evidence base. The lack of detailed reporting of turnaround times limits the ability to evaluate the operational feasibility of many emerging SSI diagnostic technologies in real-world clinical settings. Rapid diagnostics, particularly those delivering results within an hour, may be critical for timely decision-making in surgical environments, whereas technologies with longer turnaround times may be better suited for post-operative monitoring or research applications.

Product/test name	Turnaround time
KirbyBauer disc difusion method	>16 hours
Xpert® MRSA/SA SSTI	62 mins
Elecsys IL-6 assay	18 mins
Nanopore Sequencing	14 hours
Metagenomic Next-generation Sequencing	'Fast'
MALDI Biotyper system with pretreatment membrane filtration (BACpro®)	30 mins
Digital Biomarkers measured via investigational device	7 days
PET radiotracer	2 hours
Multiplex PCR method	48 hours +
Fluorescent-conjugated antibodies	30 mins

Table 3. Reported turnaround times for SSI diagnostic technologies

Developer Location

The SSI diagnostic technologies identified in this horizon scan were developed across a diverse range of countries. The United States was the most frequently reported developer location (n=9), followed by Japan (n=4). China and Germany were each reported as the developer location for four technologies, followed by the UK with two technologies (See Table 4 for technologies developed in USA and UK).

Several other countries were represented by a single technology, including Egypt, Finland, Italy, Nigeria, Pakistan, India, Portugal, Spain, and Taiwan, highlighting the global distribution of innovation in SSI diagnostics.

Overall, these findings demonstrate a strong concentration of development in high-income countries, particularly the USA, Japan, and Western Europe, with additional contributions from emerging economies. This geographic distribution may influence the regulatory pathways, clinical validation settings, and eventual applicability of these technologies in different healthcare systems, including the UK.

Product / Test name	Developer Name	Developer Location
Carbon-13 breath delta value	King's College London	UK
PET radiotracer	University of Nottingham	UK
Next generation sequencing	Northern Louisiana Men's Health Fellowship-Willis Knighton Health System	USA
Next generation sequencing and isothermal microcalorimetry for identification of bacteria	University of Alabama	USA
Nanopore Sequencing	Division of Surgical Research, Department of Surgery, Mayo Clinic, Rochester, Minnesota	USA
Xpert® MRSA/SA SSTI	Cepheid	USA
Medium enriched for newly synthesized antibodies (MENSA)	University of Colorado	USA
Fluorescent-conjugated antibodies	Rhode Island Hospital	USA
Electrochemiluminescent Immunoassay method (Abbott)	Abbott	USA
Digital Biomarkers measured via investigational device	Crely	USA
Sysmex XN hematology analysers and Cobaz analyser	University of Miami	USA

Table 4. SSI diagnostic technologies developed in USA and UK

Sample Types

The data from this horizon scan reflect the frequency of sample types used across the identified SSI diagnostic technologies. Blood samples were the most commonly reported (n=8), followed by skin/wound swab samples (n=5), while six technologies did not specify a sample type (NR – not reported). A subset of technologies (n=4) used multiple sample types, including combinations such as tissue and blood; blood and surgical discard tissue; explants, synovium, and tissue, and various types of tissue samples. Less frequently used samples included vital signs (blood pressure, body temperature, heart rate), pus, and bile, with single reports of serum, drainage fluid, breath, peritoneal samples, and plasma (Figure 3).

Overall, this distribution highlights that most SSI diagnostic technologies rely on easily accessible biological samples, such as swabs and blood, while a smaller subset of technologies explores more complex or invasive sample types. Technologies using multiple sample types may offer broader diagnostic coverage but could face additional practical or logistical challenges in clinical implementation.

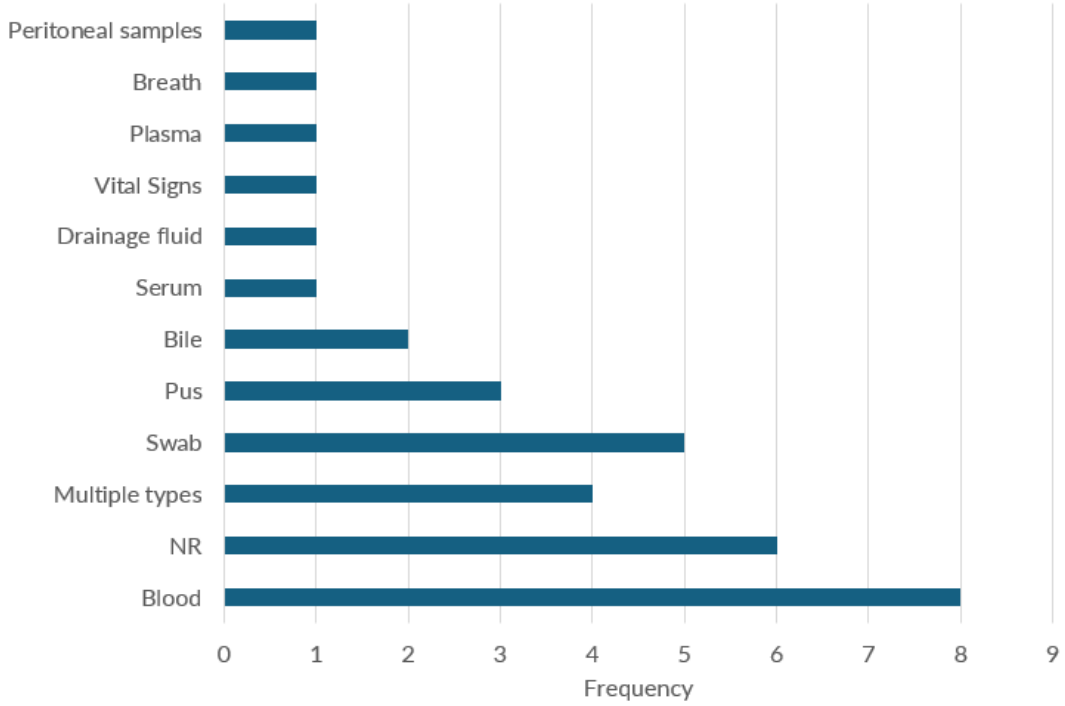

Figure 3. Frequency of sample types used in SSI diagnostic technologies

Diagnostic Accuracy

Diagnostic accuracy data were available for 18 technologies included in this scan. These were distributed across the technology categories as follows: PCR and sequencing (n=6), analytical assays (n=11), and other diagnostic techniques (n=1). Key metrics such as sensitivity,

specificity, area under the curve (AUC), positive predictive value (PPV), and negative predictive value (NPV) are shown in Figure 4.

The only test reporting likelihood ratios was a blood-based presepsin assay using the PATHFAST™ immunoanalyser developed by PHC Corporation, with a positive likelihood ratio of 2.77 and a negative likelihood ratio of 0.31.

Among the diagnostic groups, PCR and sequencing-based technologies, including multiplex PCR and FDA-approved Xpert® MRSA/SA SSTI, achieved the highest accuracy, with sensitivities and specificities approaching or reaching 100%. In contrast, biomarker-based analytical assays (e.g., IL-6, presepsin) exhibited more variable performance, some demonstrated very high sensitivity (up to 98%), but specificity was often limited.

Five of the 18 diagnostic tests with available accuracy data incorporated AMR detection, highlighting an added advantage over standard culture, which typically requires additional testing to determine antimicrobial susceptibility. They include 16S rRNA sequencing, Xpert® MRSA/SA SSTI, Unyvero IAI test, Matrix-Assisted Laser Desorption Ionization-Time of Flight (MALDI-TOF) mass spectrometry coupled with whole genome sequencing, and Multiplex PCR method.

Both 16S rRNA sequencing and a multiplex PCR method achieved perfect accuracy (sensitivity and specificity 100%). The Unyvero IAI PCR test showed strong performance for peritonitis, with sensitivity 91% and specificity 100%. MALDI-TOF coupled with whole genome sequencing (WGS) provided broad AMR gene detection with good sensitivity (97%) but lower specificity (65%) (Figure 4).

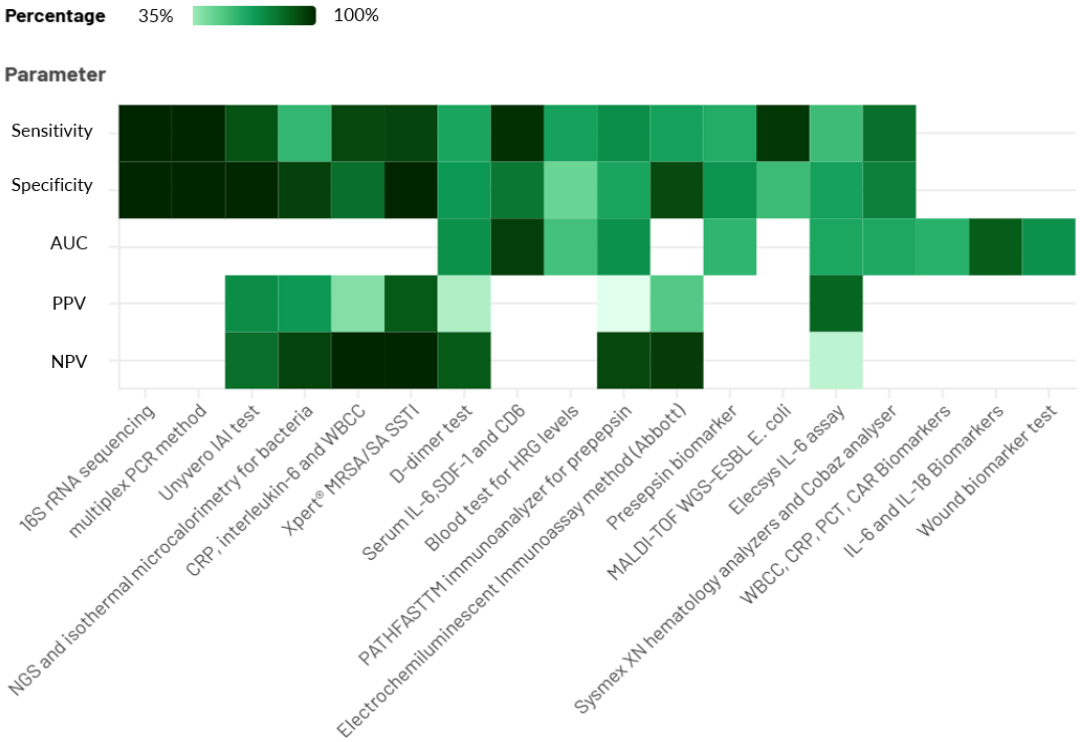

Figure 4. Heatmap showing diagnostic accuracy metrics for SSI technologies. Midpoints were used for ranges where exact values were not reported.

Conditions

Our search identified 19 distinct condition categories associated with SSI diagnostic technologies. The most frequently represented was spinal surgery (n=5), followed by orthopaedic surgery (n=4), general surgery (n=3) and gastrointestinal surgery (n=3). Other condition categories included skin and soft tissue infections (n=3), post-surgery complications (n=2), pancreatic surgery (n=2), and liver surgery (n=2). Less frequently represented were abdominal surgery (n=1), abdominal infections (n=1), breast surgery (n=1), cardiac surgery (n=1), dermatology (n=1), hepatobiliary and pancreatic surgery (n=1), liver transplantation (n=1), obstetric infections (n=1), penile prosthesis surgery (n=1), and transplantation (n=1). Within these broader categories, more specific surgical procedures were noted, such as colorectal cancer surgery and liver resection.

Populations

The populations studied were varied and diverse, often reflecting the country of development or patients with specific surgical needs. However, population reporting was limited, only 32% of studies (n=11) included details relating to age groups. Of these, only around 8% (n=3) explicitly included paediatric patients, with the majority focusing on adults.

Geographic recruitment was also inconsistently reported. Only seven studies described the study location and restricted inclusion to patients from specified countries or hospitals. Two studies were limited to elective procedures, while three included patients undergoing either elective or emergency surgery. This variability highlights the lack of standardisation in study populations and the challenges of assessing generalisability across healthcare settings.

Discussion

This horizon scan highlights the breadth of innovation in SSI diagnostics, spanning established technologies, such as PCR and sequencing-based technologies, to emerging innovations like biosensors. PCR and sequencing-based technologies demonstrated the highest diagnostic accuracy; however, many promising innovations remain at early or intermediate technology readiness levels (TRLs), with limited clinical validation and uncertain pathways to implementation. Furthermore, the adoption of PCR and sequencing-based platforms is often constrained by infrastructure and resource requirements, which may limit their widespread use in routine clinical practice.

The broader context in which these innovations are developing has important implications for their translation into practice. Political momentum around AMR has driven policies that

increasingly prioritise rapid diagnostics, but regulatory frameworks remain fragmented, with novel technologies such as metagenomic sequencing and AI-assisted biomarker interpretation lacking standardised approval pathways. Beyond regulatory challenges, economic constraints in resource-limited settings further complicate adoption. Economically, the scalability of these technologies will depend on balancing high performance with affordability, as resource-intensive sequencing approaches may limit uptake in lower-income settings, whereas immunoassays and biosensors could provide more cost-sensitive alternatives if validated robustly.

Social considerations, such as clinician confidence in novel technologies such as new biosensors or emerging biomarkers, patient safety concerns, and equitable access across diverse populations, are critical to successful implementation. However, the limited evidence on diverse populations, particularly paediatric patients and those in low-resource healthcare systems, constrains the generalisability of current findings and may affect adoption across different clinical contexts. Technological advances are accelerating rapidly, but turnaround time remains a key challenge; only a minority of technologies reported this parameter, and several offered results too slowly to be actionable in urgent surgical contexts. Emerging technologies such as Elecsys IL-6 assay and MALDI Biotyper system aim to address this gap, delivering results within minutes, thereby enabling more timely clinical decision-making.

Legal and regulatory uncertainties further complicate the pathway from prototype to practice. Established technologies such as PCR benefit from well-defined regulatory routes, whereas novel platforms face ambiguous approval criteria, slowing translation. Finally, sustainability considerations, including resource use, laboratory waste, and cold-chain logistics, will shape the scalability of diagnostic platforms. Simple, rapid assays with minimal consumables may be better suited for environmentally conscious, resource-limited, or remote healthcare environments. However, balancing sustainability with diagnostic accuracy and scalability remains a significant challenge.

An important consideration emerging from this horizon scan is the extent to which pathogen-targeting technologies align with global AMR priorities. Many of the technologies identified focus on organisms included in the WHO priority pathogen list, particularly Pseudomonas aeruginosa, Klebsiella pneumoniae, Enterobacter spp., and methicillin-resistant Staphylococcus aureus (MRSA). Technologies such as 16S rRNA sequencing, nanopore sequencing, and metagenomic next-generation sequencing demonstrate capacity to detect critical-priority pathogens, while technologies including Xpert MRSA/SA SSTI, PCR, and MALDI-TOF mass spectrometry are more commonly applied to high-priority pathogens. This alignment suggests that innovation in SSI diagnostics is not occurring in isolation but is broadly responsive to global AMR research and development priorities. Importantly, technologies capable of rapidly identifying resistant gram-negative pathogens and MRSA may play a dual role in both improving SSI management and strengthening surveillance of WHO-designated priority pathogens.

Overall, while the diagnostic landscape is dynamic and diverse, progress towards clinical adoption is uneven. Established molecular methods continue to dominate, while biosensors and analytical assays require more evidence, particularly regarding accuracy, turnaround time, and clinical feasibility.

This horizon scan has several limitations. Inconsistent reporting of key data, including turnaround time and diagnostic accuracy, hindered direct comparison across technologies. TRLs were assigned retrospectively from available descriptions rather than through formal validation, introducing potential subjectivity. Limiting the review to English-language sources may have introduced geographic bias and overlooked innovations from non-English-speaking regions, though the use of translation tools in future reviews could help mitigate this.

Implications and Recommendations

The findings of this scan suggest that SSI diagnostics hold significant potential to improve perioperative care by enabling earlier infection detection, guiding antimicrobial use more effectively, and reducing the burden of AMR. However, without deliberate action to address the current evidence gaps, regulatory uncertainty, and operational barriers, many promising innovations may struggle to progress beyond research settings.

Future development should prioritise robust clinical validation through large-scale, multicentre studies to establish diagnostic accuracy, reproducibility, and cost-effectiveness, particularly for newer technologies such as biosensors. Clearer regulatory and implementation pathways will also be critical, especially for AI-assisted diagnostics, where approval frameworks remain underdeveloped. At the same time, equity must remain central; fostering technology transfer, collaborative funding, and cost-sensitive design will help ensure innovations are accessible beyond high-income countries.

Operational feasibility will be key to adoption in practice, highlighting the need for future studies to consistently report turnaround times, sample requirements, and workflow considerations. In parallel, harnessing advances in digital health and artificial intelligence could support the rapid interpretation of complex diagnostic data, turning laboratory outputs into clinically actionable insights.

By strengthening evidence, clarifying regulatory expectations, and embedding equity and operational practicality into the development process, stakeholders can accelerate the translation of SSI diagnostic innovations into real-world benefits, ultimately improving surgical outcomes and supporting the global response to AMR.

Conclusion

SSIs remain a significant source of postoperative morbidity, prolonging recovery and increasing healthcare burden. Within this context, AMR is an escalating issue that challenges treatment

efforts and heightens the need for enhanced diagnostics and improved antimicrobial stewardship. This horizon scan demonstrates that SSI diagnostic innovation spans a wide spectrum, from mature molecular platforms already embedded in practice to experimental biosensors at early development stages. PCR and sequencing-based approaches remain the most accurate, but the majority of technologies identified are still at mid-level readiness, with limited validation in clinical settings. Development is globally distributed, though heavily concentrated in high-income countries such as the USA, Germany, Japan, and China.

Collectively, these findings suggest that the SSI diagnostic landscape is entering a phase of technological expansion, but clinical translation will require greater emphasis on validation and regulatory alignment.

Appendix A

Bibliographic database searches

Embase (Ovid)

Embase <1974 to 2025 May 28>

#	Query	Results from 28 May 2025
1	(((microbial antibiotic resistance or antimicrobial drug resistance* or antibiotic resistance or antibacterial drug resistance* or antibacterial resistance or antibiotic non?susceptibility or bacterial drug resistance* or bacterial resistance* or bacterium resistance* or microbial drug resistance or Antimicrobial resistance or Antifungal or Anti?Fungal or Fungicid* or Antifungic or Anti?fungic or antiseptic* or Anti?Infective or Biomarker or Biological Marker* or Molecular Marker or Signature Molecule* or Plasma concentration or Interleukin-6 or B-Cell Stimulatory Factor-2 or BSF-2 or Hepatocyte-Stimulating Factor or Hybridoma Growth Factor or IFN-beta 2 or IL-6 or IL6 or MGI-2 or Myeloid Differentiation-Inducing Protein or B Cell Stimulatory Factor-2 or B Cell Differentiation Factor or Interferon beta 2 or Hepatocyte stimulating factor or Plasmacytoma growth factor or Serious Bacterial Infections or SBIs or Escherichia coli or Bacterium coli or E coli or Enterococcus coli or Staphylococcus aureus or Staphylococcus pyogenes aureus or Micrococcus pyogenes or Micrococcus aureus or Staph aureus or Staphylococcus citreus or Klebsiella spp or Calymmatobacterium or Donovania or Hyalococcus or Acinetobacter spp or Streptococcus agalactiae or Streptococcus Group B or Group B streptococcus or Streptococcus difficilis or group b strep or b group streptococcus or strep agalactiae or Streptococcus pneumoniae or Diplococcus pneumoniae or Pneumococcus or Micrococcus pneumoniae or Pneumococcal or resistant organi?m* or carbapenemase producing bacteria or cytokines or Microbiom* or Clostridium difficile or Clostridioides difficile or C diff or superbugs or (Carbapenem-resistant and (enterobacterales or acinetobacter baumannii)) or Cephalosporin-resistant enterobacterales or (Fluoroquinolone-resistant and (salmonella typhi or shigella spp or non-typhoidal salmonella)) or (Methicillin-resistant and staphylococus aureus) or (Macrolide-resistant and (Group A streptococci or Streptococcus pneumoniae)) or (Ampicillin-resistant and Haemophilus influenzae) or (Penicillin-resistant and Group B Streptococci) or (MRSA or methicillin-resistant staphylococcus aureuseb) or carbapenem-resistant or Fluoroquinolone-resistant or Cephalosporin-resistant or Methicillin-resistant or Macrolide-resistant or Ampicillin-resistant or Penicillin-resistant or Bactericidal or Bacteriocides or Bactericides or Anti?Mycobacterial or antimycobacterial).ab,ti. or (*antibiotic resistance/ or *antifungal agent/ or *fungicide/ or *antiinfective agent/ or *biological marker/ or *molecular marker/ or *interleukin 6/ or *B lymphocyte differentiation factor/ or *alpha2b interferon/ or *bacterial infection/ or *Escherichia coli/ or *Staphylococcus aureus/ or *Klebsiella/ or *Streptococcus agalactiae/ or	5,061

	*group B streptococcal infection/ or *Streptococcus pneumoniae/ or *pneumococcal infection/ or *carbapenemase producing enterobacteriaceae/ or *cytokine/ or *microbiome/ or *bactericidal activity/ or *bactericide/ or *antimycobacterial agent/)) and (((surgical site adj2 infection*) or (deep surgical adj2 infection*) or (organ space adj2 infection*) or surgical infection* or SSI or SSIs or (post?operative adj2 wound infection)).ti,ab. or (surgical infection/ or postoperative infection/ or deep surgical site infection/ or organ space infection/ or superficial surgical site infection/))) adj4 ((diagnos* or Diagnostic Accurac* or Diagnostic test accuracy or Accuracy of Diagnos* or accuracy diagnostic* or Detect* or Monitor* or identif* or recogni* or assess*).ab,ti. or (*diagnosis/ or *diagnostic accuracy/ or *fungal detection/ or *bacterium detection/ or *monitoring/))	
2	(rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset$1).ti. and animal experiment/	1,301,309
3	animal experiment/ not (human experiment/ or human/)	2,744,533
4	2 or 3	2,826,295
5	(systematic review or meta-analysis).pt.	0
6	meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	756,074
7	((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	498,981
8	((quantitative adj3 (review* or overview* or synthes*)) or (research adj3 (integrati* or overview*))).ti,ab,kf.	22,584
9	((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	65,121
10	(data synthes* or data extraction* or data abstraction*).ti,ab,kf.	62,038
11	(handsearch* or hand search*).ti,ab,kf.	14,608
12	(mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	54,762
13	(met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	24,230
14	(meta regression* or metaregression*).ti,ab,kf.	22,394

15	(meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp,hw.	891,807
16	(medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,hw.	551,802
17	(cochrane or (health adj2 technology assessment) or evidence report).jw.	32,789
18	(comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	31,806
19	(outcomes research or relative effectiveness).ti,ab,kf.	18,089
20	((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	8,758
21	(multi* adj3 treatment adj3 comparison*).ti,ab,kf.	473
22	(mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf.	266
23	umbrella review*.ti,ab,kf.	2,893
24	(multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	37
25	(multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	22
26	(multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	31
27	or/5-26	1,189,698
28	retrospective study/ or case report/ or exp case control study/	5,099,375
29	((retrospective adj7 (study or studies or design or analysis or analyses or data or review)) or ((case adj3 (report or reports or study or studies or histories)) or ((case adj control) or (case adj comparison) or (case adj controlled) or (case-referent adj3 (study or studies or design or analysis or analyses))))).ti,ab,kf.	2,730,318
30	28 or 29	5,744,923
31	4 or 27 or 30	9,598,036
32	1 not 31	3,018
33	limit 32 to english language	2,744
34	limit 33 to yr="2021 -Current"	693

IEEE Xplore

Searched 28-05-25

("Index Terms":antibiotic resistance) OR ("Publication Title":"microbial antibiotic resistance" OR "Publication Title":"antimicrobial drug resistance" OR "Publication Title":"antibiotic resistance" OR "Publication Title":"antibacterial drug resistance" OR "Publication Title":"antibacterial resistance" OR "Publication Title":"antibiotic non susceptibility" OR "Publication Title":"bacterial drug resistance" OR "Publication Title":"bacterial resistance") OR ("Abstract":"microbial antibiotic resistance" OR "Abstract":"antimicrobial drug resistance" OR "Abstract":"antibiotic resistance" OR "Abstract":"antibacterial drug resistance" OR "Abstract":"antibacterial resistance" OR "Abstract":"antibiotic non susceptibility" OR "Abstract":"bacterial drug resistance" OR "Abstract":"bacterial resistance") AND ("Publication Title":diagnostic OR "Publication Title":diagnosis OR "Publication Title":"Diagnostic Accuracy" OR "Publication Title":"Diagnostic test accuracy" OR "Publication Title":"Accuracy of Diagnosis" OR "Publication Title":"accuracy diagnostic" OR "Publication Title":Detect OR "Publication Title":Monitor OR "Publication Title":identification OR "Publication Title":assess) AND ("Abstract":diagnostic OR "Abstract":diagnosis OR "Abstract":"Diagnostic Accuracy" OR "Abstract":"Diagnostic test accuracy" OR "Abstract":"Accuracy of Diagnosis" OR "Abstract":"accuracy diagnostic" OR "Abstract":Detect OR "Abstract":Monitor OR "Abstract":identification OR "Abstract":assess) AND ("All Metadata":postoperative infection) OR ("All Metadata":surgical site infection) OR ("All Metadata":organ space infection) OR ("All Metadata":surgical wound infection)

Filters Applied: Journals 2021 – 2025

Hits - 42

Cochrane CENTRAL

Search Name: AMR + SSI v2

Date Run: 28/05/2025 19:44:15

Comment: AMR + SSI search

ID Search Hits

#1 ((("microbial antibiotic resistance" or antimicrobial drug resistance* or "antibiotic resistance" or antibacterial drug resistance* or "antibacterial resistance" or antibiotic non?susceptibility or bacterial drug resistance* or bacterial resistance* or bacterium resistance* or "microbial drug resistance" or "Antimicrobial resistance" or Antifungal or Anti?Fungal or Fungicid* or Antifungic or Anti?fungic or antiseptic* or Anti?Infective or Biomarker or Biological Marker* or "Molecular Marker" or Signature Molecule* or "Plasma concentration" or "Interleukin-6" or "B-Cell Stimulatory Factor-2" or "BSF-2" or "Hepatocyte-Stimulating Factor" or "Hybridoma Growth Factor" or IFN-beta 2 or IL-6 or IL6 or MGI-2 or Myeloid Differentiation-Inducing Protein or B Cell Stimulatory Factor-2 or B Cell Differentiation Factor or Interferon beta 2 or Hepatocyte stimulating factor or Plasmacytoma growth factor or Serious Bacterial Infections or SBIs or Escherichia coli or Bacterium coli or E

coli or Enterococcus coli or Staphylococcus aureus or Staphylococcus pyogenes aureus or Micrococcus pyogenes or Micrococcus aureus or Staph aureus or Staphylococcus citreus or Klebsiella spp or Calymmatobacterium or Donovania or Hyalococcus or Acinetobacter spp or Streptococcus agalactiae or Streptococcus Group B or Group B streptococcus or Streptococcus difficilis or group b strep or b group streptococcus or strep agalactiae or Streptococcus pneumoniae or Diplococcus pneumoniae or Pneumococcus or Micrococcus pneumoniae or Pneumococcal or resistant organi?m* or carbapenemase producing bacteria or cytokines or Microbiom* or Clostridium difficile or Clostridioides difficile or C diff or superbugs or (Carbapenem-resistant and (enterobacterales or acinetobacter baumannii)) or Cephalosporin-resistant enterobacterales or (Fluoroquinolone-resistant and (salmonella typhi or shigella spp or non-typhoidal salmonella)) or (Methicillin-resistant and staphylococus aureus) or (Macrolide-resistant and (Group A streptococci or Streptococcus pneumoniae)) or (Ampicillin-resistant and Haemophilus influenzae) or (Penicillin-resistant and Group B Streptococci) or (MRSA or methicillin-resistant staphylococcus aureuseb) or carbapenem-resistant or Fluoroquinolone-resistant or Cephalosporin-resistant or Methicillin-resistant or Macrolide-resistant or Ampicillin-resistant or Penicillin-resistant or Bactericidal or Bacteriocides or Bactericides or Anti?Mycobacterial or antimycobacterial))):ti,ab,kw (Word variations have been searched) 158360

#2 MeSH descriptor: [Drug Resistance, Microbial] this term only 925

#3 MeSH descriptor: [Antifungal Agents] this term only 2278

#4 MeSH descriptor: [Anti-Infective Agents] this term only 3237

#5 MeSH descriptor: [Interleukin-6] this term only 4359

#6 MeSH descriptor: [Interferon alpha-2] this term only 1920

#7 MeSH descriptor: [Bacterial Infections] this term only 3717

#8 MeSH descriptor: [Biomarkers] this term only 21000

#9 MeSH descriptor: [Escherichia coli] this term only 906

#10 MeSH descriptor: [Staphylococcus aureus] this term only 862

#11 MeSH descriptor: [Klebsiella] this term only 68

#12 MeSH descriptor: [Streptococcus agalactiae] this term only 147

#13 MeSH descriptor: [Streptococcal Infections] this term only 758

#14 MeSH descriptor: [Streptococcus pneumoniae] this term only 776

#15 MeSH descriptor: [Pneumococcal Infections] this term only 803

#16 MeSH descriptor: [Carbapenem-Resistant Enterobacteriaceae] this term only 15

#17 MeSH descriptor: [Cytokines] this term only 4546

#18 MeSH descriptor: [Microbiota] this term only 639

#19 MeSH descriptor: [Clostridioides difficile] this term only 303

#20 MeSH descriptor: [Anti-Bacterial Agents] this term only 15191

#21 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 171236

#22 MeSH descriptor: [Surgical Wound Infection] this term only 4506

#23 ((surgical site adj2 infection*) or (deep surgical adj2 infection*) or (organ space adj2 infection*) or surgical infection* or SSI or SSIs or (post?operative adj2 wound infection)):ti,ab 13508

#24 #22 or #23 16005

#25 MeSH descriptor: [Diagnosis] this term only 79

#26 ((diagnos* or Diagnostic Accurac* or "Diagnostic test accuracy" or Accuracy of Diagnos* or accuracy diagnostic* or Detect* or Monitor* or identif* or recogni* or assess*)):ti (Word variations have been searched) 97084

#27 #25 or #26 97125

#28 #21 and #24 and #27 with Publication Year from 2021 to 2025, in Trials 39

Clinical Trials

US Clinical Trial Register

URL: https://clinicaltrials.gov/

A search was conducted on ClinicalTrials.gov on 16th June 2025 using the terms *"Surgical Wound" OR "Surgical Site Infection" OR "surgical site infection after major surgery" OR surgery – complications*. Due to ClinicalTrials.gov's feature of searching for synonyms, the query also included related terms such as Surgical Site Infections; Postoperative Wound Infection; Post Operative Wound Infection; infected surgical wounds; Postoperative Wound Infections, and others. The search was limited to study phase 2-4 and 'not applicable' and limited between clinical trial registration date range 01-01-2021 – 06-16-2025. These studies were uploaded to Rayyan by an Information Specialist for screening by reviewers.

WHO clinical trial registry

URL: https://trialsearch.who.int/AdvSearch.aspx

The search was conducted using the WHO International Clinical Trials Registry Platform. Phases 2, 3, and 4 were selected using the control + click function. The following search string was entered into the Condition field: *surgical wound or surgical site infection or postoperative wound infection* in the Title field of the advanced search. The date of registration was limited using the calendar tool. The results were downloaded as a CSV file and saved for further assessment.

Appendix B

Full list of SSI diagnostic technologies

Product / test name	Developer	TRLs
16S rRNA sequencing	Department of Plant Biology and Biotechnology, University of Benin, Ugbowo, Benin City, Nigeria	9
Next generation sequencing	Northern Louisiana Men's Health Fellowship-Willis Knighton Health System	9
Blood test for presepsin with the PATHFASTTM immunoanalyzer	PHC corporation	9
Electrochemiluminescent Immunoassay method	Abbott	9
Presepsin biomarker	Department of Anaesthesiology, Yamagata University Faculty of Medicine, Yamagata, Japan	9
KirbyBauer disc difusion method	National Institute for Biotechnology and Genetic Engineering College, Pakistan	9
Sysmex XN haematology analysers and Cobaz analyser	University of Miami	9
Xpert® MRSA/SA SSTI	Cepheid	9
Elecsys IL-6 assay	Roche Diagnostics (Shanghai) Ltd.	7
Polymerase chain reaction (PCR)	Sohag University	6
Unyvero IAI test	Curetis	6
Next generation sequencing and isothermal microcalorimetry for identification of bacteria	University of Alabama	6
Smear test and PCR	Clinic, Neurosurgical, University of Munich (LMU), Campus Grosshadern, Marchioninistrasse 15, 81377, Munich, Germany	6
Nanopore Sequencing	Division of Surgical Research, Department of Surgery, Mayo Clinic, Rochester, Minnesota, USA	6
Metagenomic Next-generation Sequencing	Division of Infectious Diseases, Department of Internal Medicine, Taichung Veterans General Hospital, Taichung, Taiwan, R.O.C.;	6
Medium enriched for newly synthesized antibodies (MENSA)	University of Colorado, (USA)	6
D-dimer	University of Cantabria	6
Serum IL-6,SDF-1 and CD6	Yantaishan Hospital	6
Blood test for HRG levels	Okayama University	6
MALDI Biotyper system with pretreatment membrane filtration (BACpro®)	Department of Biochemistry, School of Life and Environmental Science, Azabu University, Kanagawa, Japan	6
Matrix-Assisted Laser Desorption Ionization-Time of Flight (MALDI-TOF) mass spectrometry, MiSeq V3 chemistry (whole genome sequencing)	Brucker daltonics/Illumina/Université Catholique de Louvain UCLouvain	6
IL-6 and IL-18 Biomarkers	Central South University	6
CRP biosensor	Pingdu People's Hospital	6

Digital Biomarkers measured via investigational device	Crely	6
PET radiotracer	University of Nottingham	6
16s rRNA Next Generation Sequencing	Hannover Medical School	5
Carbon-13 breath delta value	King's College London	5
Wound biomarkers: IL-1 α, IL-1 β, IL-4, IL-10, IL-13, tumour necrosis factor alpha (TNF-α), transforming growth factor beta1 (TGF-β1), vascular endothelial growth factor (VEGF) C and D	Herantis Pharma	5
Multiplex PCR method	Tokyo University of Pharmacy and Life Sciences	4
Fluorescent-conjugated antibodies	Rhode Island Hospital	4
D-Lactate biomarker	University of Verona, Italy	4
WBCC, CRP, PCT, CAR Biomarkers	Hospital Braga, General Surgery, 2 Hospital Trofa Saude, General Surgery, Portugal	4
Novel medical device	Madras Medical College, India	4
CRP, LK, PCT and TNF-a	Universitätsmedizin Göttingen, Klinik für Unfallchirurgie, Orthopädie und Plastische Chirurgie, Göttingen, Deutschland	3

References

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3 GOV.UK. *Antimicrobial resistance a deadly threat*. 2016. Available from: https://www.gov.uk/government/news/antimicrobial-resistance-a-deadly-threat-warns-chancellor#:~:text=By%202050%2C%20antimicrobial%20resistance%20could,cumulative%20cost%20of%20%24100%20trillion. [Accessed 07/08/2025].

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