Horizon Scanning Final Report: Identification of Surgical Site Infection Technologies

Authors: Lucy Barrass, Abigail Roberts, Oluwatomi Arisa, Emily Robertson, Aoife Oliver, Oshin Sharma, Akvile Stoniute, Janet Kinnersley, James Woltmann, and Dawn Craig

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Professor Dawn Craig
Director

T: +44(0) 191 208 2259
E: info@io.nihr.ac.uk
www.io.nihr.ac.uk

NIHR | Innovation Observatory

Newcastle University

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Introduction

The NIHR Innovation Observatory (IO) has completed the horizon scanning of the final of four clinical pathways for the identification of technological innovations (e.g., products/interventions) that have the potential to reduce demand for antimicrobials through infection prevention, detection, and/or management intervention.

The innovation landscape presented for surgical site infection (SSI), aims to inform decisions by NHSE & I's AMR Programme Board, and accelerate adoption of proven innovations that will enhance appropriate antimicrobial prescribing and improve patient outcomes. This report (accompanied with the complete Excel SSI datasets) provides important, immediately relevant data on key areas of development, to allow readers to evaluate the potential impact of these innovations and identify promising technologies for use in the NHS (or wider). To help with clarity and comprehensibility, the report has been organised and presented into three main sections:

1. Methods – Horizon scanning strategy – an overview of the search strategy devised to identify technologies related to SSI and their related evidence

2. Results – SSI technology landscape – including the clinical trial, product pipeline, patent, and funding landscape result sections, each containing information (including visualised data) about the global landscape of SSI technological innovations

3. Conclusion – Summary of key themes and emerging patterns, based on the results retrieved from the scan and market intelligence

It is hoped that the visualisations and accompanying narrative presented in this report (along with the complete dataset) inform understanding and shape discussions on the availability of innovative technologies for SSI. The report also describes some of the key providers/developers in play for the international market and offers a snapshot of current products, including those with high innovation potential.

Methods

Horizon Scanning for Surgical Site Infection Technologies

The horizon scanning methodologies developed by the IO to identify the pipeline of SSI technologies involved the identification of information sources that detected 'signals' for SSI technologies. The collection of primary and secondary sources were systematically scanned using a combination of traditional scanning methods (manual), automated, and novel AI/machine learning techniques.

Collation of Key Terms

Specific search strategies were formulated for the scans, combining identified MeSH/key terms with Boolean operators (where applicable). A comprehensive list of keywords and concepts was compiled by the IO's Information Specialist Team, based on the evidence reports provided by the AMR Programme Board, in addition to key, identified publications/reports. The primary

concepts and terms identified, *inter alia*, related to surgical site infection, surgical wound infection, surgical infection, wound infection, post-operative wound monitoring and wound assessment, cellulitis, patient generated health data, wearable electronic devices, telemedicine, and digital imaging.

The set of systematic searches were performed in February 2022 and no date/period exclusions were applied to the searches (unless otherwise stated). Based on successive screening of sources (i.e., identification of SSI technologies), information was extracted and imported for further data processing.

Inclusion criteria

All technological innovations included in the scan had to meet the criteria for a medical technology (e.g., device, diagnostic test, digital or a combination) intended for the monitoring or detection of SSI, including technologies for remote monitoring. Following consultation with the AMR Board, it was agreed that technologies for the prevention or treatment of SSI would be excluded from the primary dataset and, if found as part of our searches, would be tracked in a separate table (see 'Other Innovations' in the accompanying Excel document). All technologies were further classified (see below) and the collated information can be found within the SSI dataset (Excel file accompanying this report).

Classification of SSI technologies

- Type of technology (e.g., device, diagnostic test, digital or a combination)
- Place in clinical pathway (e.g., prevention, detection, monitoring, screening)
- Care setting (e.g., primary care, secondary care, community))
- Population (e.g., neonate, child, adult, elderly)
- Biological sample type (e.g., blood, urine)
- Pathogen target (e.g., bacterial, fungal, viral)
- Resistance markers detected
- Type of test (e.g., molecular, immunoassay, other)
- Turnaround time (sample to result)
- Method (e.g., RT-PCR, lateral flow immunoassay)

In addition to these fields, information relating to sensitivity/specificity and limit of detection was captured, where available, for diagnostic technologies, as well as clinical trial information and published evidence. Intelligence relating to funding/investment, development or competition awards, and patents was captured, as available, under 'Additional Comments' in the SSI dataset (accompanying Excel file).

Information sources used as part of these scans included (*inter alia*)

- OpenScan: IO's internal clinical trial database containing information from 51 registries across the globe (e.g., UK, Europe, USA)
- Regulatory agency sources (e.g., US FDA)
- Publications (including conference outputs)
- MedTech news websites (e.g., Fierce Biotech)

- Commercial websites and reports
- Academic institution webpages
- Patent databases
- NICE medical technologies guidance

Special Note: Developing optimal search strategies for detecting clinical studies
The initial trial scan (conducted with OpenScan), combined search terms for SSI and retrieved a high volume of clinical trial records (over 1,500). US-based trials were the most prominent and yielded the most results. In order to narrow down the search, the US-based trials were excluded from our initial search and a supplementary search was conducted on ClinicalTrials.gov (the U.S. National Library of Medicine). This secondary search, alongside the OpenScan results, retrieved 202 trials, of which 70 were found to be within the scope of the project.

Results

The Need for Improved Technologies in SSI
Surgical site infections are among the world's most common healthcare-associated infections and continue to be the second most frequent healthcare-associated infection in Europe and the United States.[1] It has been estimated that SSIs affect more than 500,000 Europeans a year at an economic cost that ranges from €1.47-19 billion.[2] They are associated with a host of patient quality of life issues, including: longer post-operative hospital stays, additional surgeries, admission to intensive care, and higher mortality.[3] While SSIs typically originate in a hospital setting, problems can arise after discharge and require readmission, which highlights the importance of community and primary care involvement as part of this clinical pathway. These standing concerns, as well as the rise in antimicrobial resistance, have emphasised the significance of SSI detection and monitoring, and accordingly, the persistent need for new technologies that can aid in both.

Product Pipeline of SSI Innovations
Our horizon scan identified 51 technologies from across 11 countries. Whilst there were only a small number of countries developing SSI technologies that fell within the scope of this scan, our analysis (based on country of development) highlighted that the US (35%, 18), UK (25%, 13), Australia (10%, 5) and France (10%, 5) were the top countries for development activity (**Figure 1**). While the bulk of US development split equally between digital technologies and diagnostics, the UK's development appeared to focus more heavily on diagnostic technologies alone. 80% of France's technologies were developed by a single company, bioMerieux, suggesting that innovation in France may be predominantly driven by this one company; their diagnostic technologies were intended for the detection of bacteria known to cause SSI.

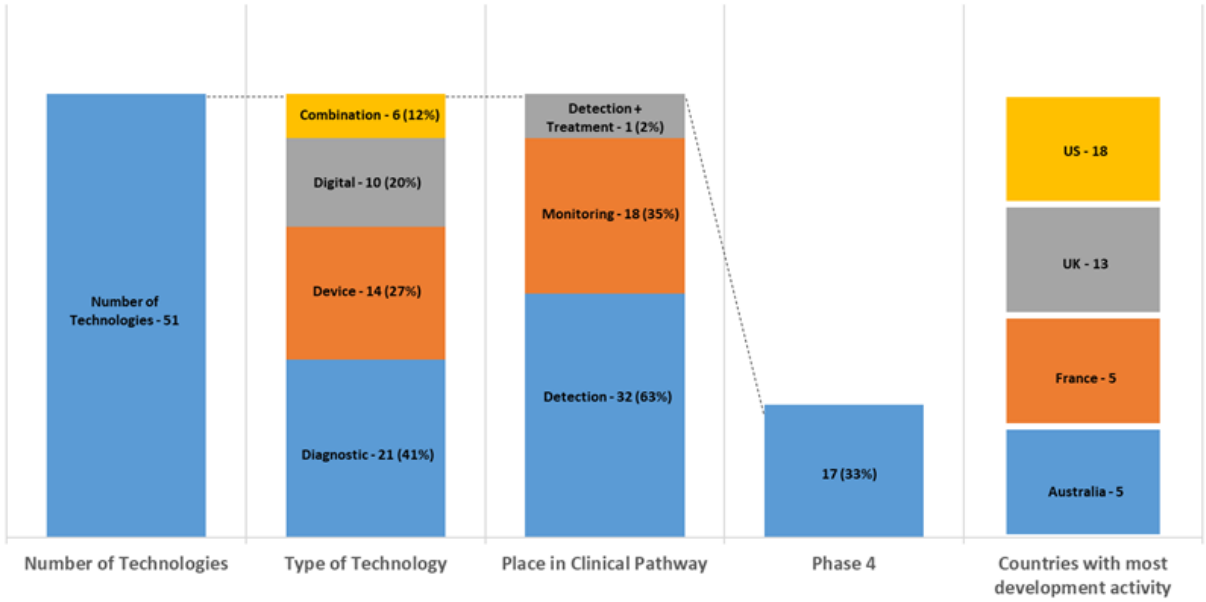

Figure 1. Insights into SSI Innovations
51 SSI technological innovations including medical devices, diagnostic tests, digital technologies (or a combination) were identified from across 11 countries. The majority of innovations were developed for the detection of SSI. Development activity was largely concentrated in the US (35%) and the UK (25%), with a considerable proportion of products (33%) on the market or ready to market (Phase 4).

All devices identified as part of this scan have been classified based on their stage of development (Phases 1-4), with Phases 3 and 4 indicative of late/mature stage of development. The majority of the devices found in our scan were in the late/mature stage, i.e. on or near ready to market, as shown in **Figure 2**, with fewer technologies in the Phase 1 Proof of Concept Stage. Overall, 10 of the 17 products in Phase 4 (mature phase) have obtained regulatory approval in 1 or more jurisdictions, with 53% of technologies in Phase 4 awarded EU approval (CE Mark).

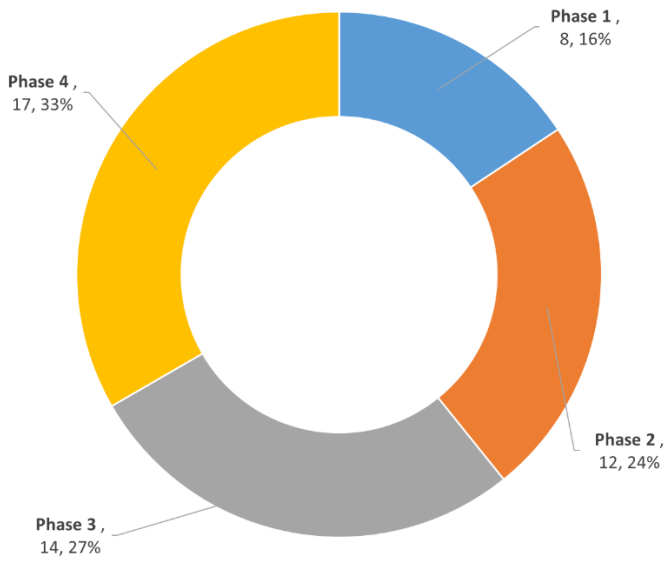

Figure 2. Doughnut chart representing the development stage of SSI technologies
In total, 51 SSI technologies were identified in the Innovations Observatory's scan. The technologies have been classified by stage of development: Phase 1 (i.e. concept) – 8, 16%; Phase 2 (i.e. prototype/early-stage research including preclinical studies) – 12, 24%; Phase 3 (i.e. product validated/demonstrated in relevant environment/clinical study) – 14, 27%; Phase 4 (i.e. product ready to launch/regulatory approved) - 17, 33%.

While the largest proportion (41%) of technologies were for use in secondary care, 5 technologies were identified that reported to specifically detect or monitor wound infections in either the home or community setting. These included a digital technology developed by RMIT University in collaboration with Bolton Clarke which uses thermal imaging as an early alert system with the aim of improving chronic wound care. Without requiring physical contact with the wound, it reduces the chance of further infection or disrupted healing, thereby allowing early infection detection without increasing the risk of such infection. It is important to note that 19 technologies in our scan were classified as having a 'Multiple' care setting, indicating a potential use across more than one care setting, and as 58% of these were intended to monitor wounds and/or infections, it is likely that they may have an application of use by patients at home. One such example is WoundLAB from Graphea, an electronic wound patch that continuously measures a patient's wound and passes that data through a smartphone app into cloud storage for their physician to review.

Of the 51 technologies identified, 17 had public information available as to their turnaround times. Nearly half of these (8) had a turnaround time of 60 minutes or less. These included 3 rapid susceptibility tests which aimed to detect resistance (i.e., RAPIDEC® by CARBA NP, Microplate by the University of Strathclyde, and New smart diagnostics for infection by Vidiia Ltd), as well as 2 technologies (KroniKare by KroniKare Limited and MolecuLight i:X by MolecuLight) that reported to detect infection in under 60 seconds using imaging techniques

and artificial intelligence. Both latter technologies were handheld devices intending to increase detection speed, but neither has demonstrated a preferred care setting.

Pipeline Insights: Technologies for AST (with or without pathogen detection)
Whilst susceptibility testing is increasingly important in the field of AMR, our horizon scan identified just 12 technologies relating to Antimicrobial Susceptibility Testing (AST). Half of these technologies included pathogen detection, while the other 6 were intended for susceptibility testing alone, and the most common technique for detection across all was molecular testing (e.g., RT-PCR, isothermal amplification). Only 2 technologies were for named resistance markers (i.e., CHROMID® VRE by bioMerieux and T2 Resistance Panel by T2 Biosystems, Inc.).

OmiX Research & Diagnostics Laboratory and Capstone Health, respectively, are working on technologies of particular interest. OmiX Research has received funding from the Longitude Prize for the development of two technologies intended for AST detection of carbapenemase-resistant bacteria and Extended Spectrum Beta Lactamase resistant bacteria. Both tests, at present, claim a turnaround time of less than 6 hours and are under late-stage development in India. Capstone Health, on the other hand, offers a commercialised Wound Care Panel (Capstone Health) which utilises RT-PCR for AST with pathogen detection. This technology was particularly interesting as it targeted more than one pathogen type (i.e., the identification of bacterial, fungal, and viral infections).

Pipeline Insights: Monitoring Innovations
Our pipeline scan identified 18 innovations specifically designed for the monitoring of patients, either remotely or in hospital. Of these, 50% were digital innovations, 28% were devices, and 22% were a combination product (e.g., digital + device). Such innovations included the Minuteful for Wound app by healthy.io, which assesses and remotely monitors a wound through a smartphone application and a combination of digital scans and 3D modelling. Another innovation using a digital application, WoundCheck, is under development by the University of Wisconsin, and it allows a patient to transmit daily surgical wound images to their clinician along with a short questionnaire about their recovery. Given improvements in telephony, digital imaging, data availability, it is likely that such innovations will become more popular and greater in number, and if their utility was not immediately obvious prior, the advent of the COVID-19 pandemic has demonstrated a clear promise of use.

Some technologies in development utilise a combination of different technology types, such as a separate device that links to a digital smartphone. VeCare by the National University of Singapore, for example, consists of a wound sensing bandage, an electronic chip, and a mobile app. The bandage detects multiple chronic wound biomarkers in wound fluid through an electrochemical system, and the integrated chip allows wireless transmission of real-time, point-of-care assessments of the wound to the supporting mobile app. The novel sensor can detect temperature, pH, bacteria type, and inflammatory factors specific to chronic wounds within 15 minutes, thereby enabling faster and more accurate wound assessment.

Pipeline Insights: Detection Innovations

There were 33 innovations that reported to detect the presence of an infection or a resistant microorganism in a wound, either a surgical site infection or otherwise. 63% of the innovations were diagnostics tests with the remainder comprising of medical devices, digital technologies, or a combination product. 22 technologies were for the detection of bacterial infections (e.g., *S. aureus*, *MRSA*, *E. faecalis*), 2 other technologies allowed for detection of both bacterial and fungal infections, and 1 technology was developed for the detection of bacterial, fungal, or viral infection (Capstone Healthcare – Wound care panel). A closer look at the data revealed that there were a wide range of detection methods, including both molecular assays (utilising techniques such as RT-PCR, biosensors, and isothermal amplification) as well as immunoassays (such as ELISA). Other detection techniques involved colourimetric sensors to detect pathogenic bacteria in wounds through fluorescence.

Clinical Trial Landscape

OpenScan, the Innovation Observatory's clinical trial tool, was used to search trial data from 51 registries across the globe (including the UK, EU, USA, and China). After an initial scoping search (for more information, please see the Methods section above), we identified 70 trials across 19 countries that met our inclusion criteria. The US (29%), UK (21%), Australia (11%), China (6%), and Sweden (6%) represented those countries with the most clinical trial activity.

The majority of results identified as part of the overarching clinical trial scan (85%) focused on prevention or/and treatment of SSI and, as such, fell out of scope of the primary dataset. Such a difference in clinical focus likely reflects the post-operative surveillance challenges associated with the detection, diagnosis, and monitoring of SSIs. Of those trials associated with prevention, many featured technologies specific to negative pressure wound therapy (NPWT), novel wound dressings, and wound protection devices. Antimicrobial dressings were also a common technology used in the prevention trials, though other technologies included humidification systems, AI models, as well as hygiene compliance systems. More information about the prevention technologies identified as part of the clinical trial scan can be found in the Other Innovations dataset (accompanying Excel file).

Of the 70 trials found, only 11 focused specifically on the unmet need of detection or monitoring of SSI, and **Figure 3** below depicts the changing clinical trial landscape of these trials (registered between 2016-2026). Though the average trial lasted less than 2 years, one US trial at the University of Colorado, Denver (NCT04897971) has been running from August 2021 and will continue to the estimated completion date of May 2026. This trial is of particular interest because it is one of the few pathogen-detecting diagnostics identified, specifically testing a new way to diagnose and track treatment of spine implant infections caused by *Staphylococcus aureus*.

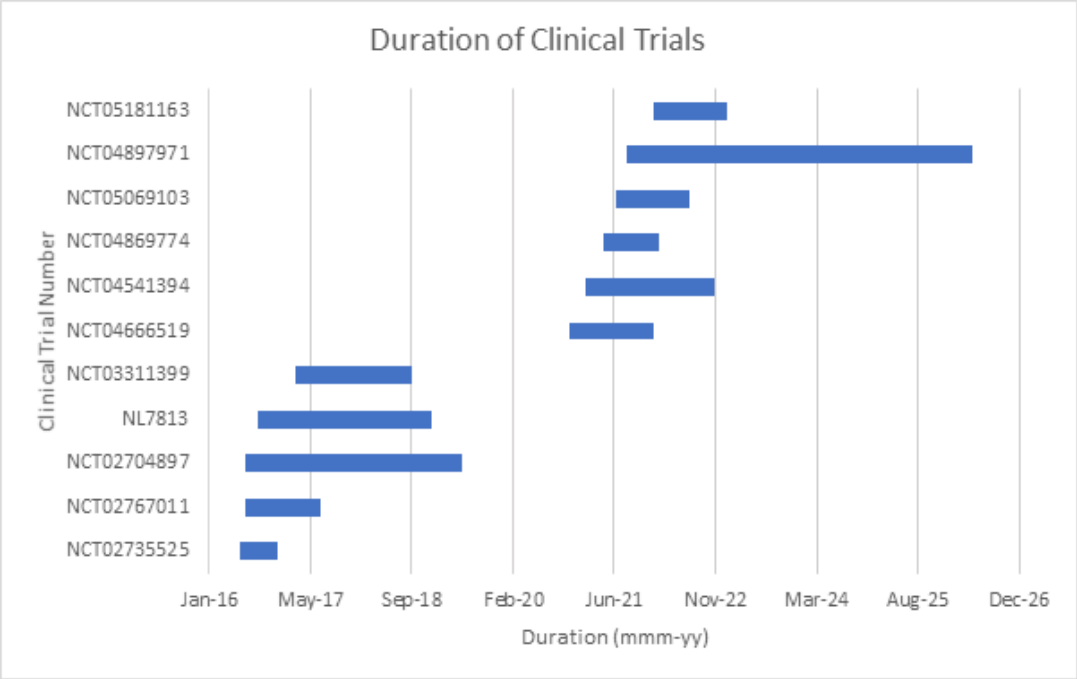

Figure 3. Evolving Clinical Trial Landscape
The clinical trial landscape (activity and duration) for SSI technological innovations.

The majority of the trial results (7, 64%) occurred in an adult and/or elderly population, and only four trials allowed children as participants, though nearly all of these specified children above the age of 16. The ELISA diagnostic test by Sohag University (NCT05181163) to detect bacteria responsible for biofilm formation was the only trial result with no specified minimum age.

Trial Insights: Tele-health & Mobile Health (mHealth)
Within the landscape of detection and monitoring, there was a focus on digital tele-health and mobile health technologies that aid the process of screening and identifying SSI in patients. Common innovations included remote wound assessment through smartphone applications and at-home monitoring systems. One such innovation is the implementation of a surgical wound tele-monitoring online tool developed at the University of Edinburgh (NCT05069103). This trial has been designed based on Medical Research Council (MRC) guidance[4] and utilizes the ISLA Visual Care online platform, which collates image data submitted by patients who are concerned about their wounds or prompted by a routine request to update. Clinicians can then access this information and review the detection or diagnosis of an SSI. Another similar innovation is a smartphone application called how2trak developed by the University of Ottawa to reduce in-person interactions during the COVID-19 pandemic. The mobile application was developed specifically for post-operative wound and symptom surveillance after colorectal surgery, with implemented patient self-assessments and virtual consultations with specialised nurses.

The majority of the clinical trials identified were intended for secondary care (55%), but there were a few innovations designed for home care (27%) and community care settings (18%). One

particular community care technology of interest was in development at the Charleston Area Medical Centre (NCT02767011). As part of this trial, patients received a tablet computer and a home monitoring sensor system that transmits patient data to a central website monitored by care managers.

Trial Insights: Antimicrobial Susceptibility Testing and Pathogen Detection

Our clinical trial scan found only one result that featured an AST technology, and that particular innovation included pathogen detection: the aforementioned ELISA kit from Sohag University (NCT05181163), which intends to detect biofilm formation and patterns of susceptibility of bacteria following orthopaedic surgery. This trial is not yet recruiting and will not be complete until 2023.

In addition to the sole AST trial result, our scan found two trials that featured pathogen-detecting technologies: MolecuLight by Taipei Medical University Shuang Ho Hospital (NCT04541394) utilizes a 405nm violet light to detect the regions of a wound where pathogenic bacterial counts are the highest, and by triggering a photoluminescent reaction, paired with a camera, the device gives results in real-time; MENSA (medium enriched for newly synthesized antibodies) developed by the University of Colorado, Denver (NCT04897971), intends to detect and differentiate between *S. aureus* infections at spinal implant sites versus *S. aureus* infections in other sites using only blood and elicited antibodies.

Patent Landscape

The data from our international patent scan revealed 2,070 patent documents in the field of SSI technological innovation. North America accounted for 45% of patents, followed by Asia (15%), and Europe (13%). The leading countries of patent filings were US (1,336) and China (432). Our data analysis showed that 27% of patent applications have worldwide patent protection through the World Intellectual Property Organization (WIPO). Since 2001, patent applications have gradually increased, reaching its peak in 2021 with 185 patent applications. There was a considerable increase of patent applications in 2010 (127) compared to previous years, which coincides with the European Centre for Disease Prevention and Control's (ECDC) 2010-11 surveillance of surgical site infections in Europe, during which the number of reported operations increased, and three countries reported such data for the first time.[5] Common patent topics included diagnostic biomarkers, SSI prediction, and alternatives for SSI detection. Other innovative patents included antibiotic/antimicrobial materials for surgical tools, wound care methods, and negative wound pressure therapy. Leading patents included alternative SSI detection methods, including Covidien's Infection Detection Device, which focused on SSI detection and SSI alerting in healthcare settings. Patents also included multifaceted devices, such as Leland Stanford Junior University's methods for SSI prevention which detects infection, the orientation of infection, and provides recommendations for treatment.

Key Providers

There appears to be an active development interest in SSI detection or monitoring tools, though it may be smaller in comparison to the research efforts in SSI preventative methods. There are a number of factors that are expected to contribute to future growth in the SSI prevention and surveillance market, including rising incidence rates of SSIs, development of advanced technologies, increase in the number of surgeries performed, and ageing populations.

Recent growth has been seen in the development of remote monitoring systems to improve remote care and to cater to the needs of the COVID-19 pandemic. Internationally, industry (small or medium-sized enterprises (SMEs) and large enterprises) and academic institutions play a key role in the development of innovative SSI technologies. The largest proportion of technologies in development were found from companies (25, 49%), followed by academic institutions (15, 29%). Our global scan identified 43 developers from across 11 countries. Key developers in this area include BioMerieux, OmiX Research and Diagnostics Laboratories Pvt Ltd, SmartWound, and RMIT University.

Our analysis showed that the UK is one of the leading countries for SSI technology development. A total of 11 UK-based developers were detected in our dataset, including key developers such as SmartWound, the University of Edinburgh, and the University of Manchester. SmartWound and the University of Edinburgh each have a development portfolio of 2 technologies for the detection of SSI. The University of Manchester is currently developing a wound dressing for in situ microbial sensing, which could provide early antibiotic susceptibility data for organisms colonising chronic wounds and provide healthcare staff with information about the antibiotic drugs most likely to work. This development is alongside WoundPad, a digital technology they have launched, in collaboration with Medical Data Solutions and Services, for monitoring complex wounds.

The global development pipeline consisted of a range of technologies, from established diagnostic devices and tests (e.g., RT-PCR, wound dressings) to new technologies (e.g., AI, fluorescent sensors, biosensors) and combined monitoring methods (e.g., digital apps). The development of new, innovative technologies presents a significant opportunity for their application in the future of early, rapid detection of SSIs and improvements in the ability to remotely monitor wounds.

From our dataset, we have identified a small selection of technologies with high potential that may have attracted significant investment and/or have been shortlisted for development awards and competitions, along with other novel technologies that may be of interest.

Table 1. New and emerging technologies for SSI of particular interest

Developer	Technology	Product Description	Location
Adiuvo Diagnostics	Illuminate	Illuminate is a rapid Point of Care device which aims to detect and classify clinically relevant pathogens on wounds.	India
Grapheal	WoundLAB	Grapheal is an electronic wound patch that continuously measures and stores wound biometric parameters, and communicates them to a medical cloud via a smartphone app.	France
KroniKare Limited	KroniKare	KroniKare is a rapid hand-held device and an AI-based system for assessment and management of chronic wounds.	Singapore
Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V.	Bacteriosafe	Bacteriosafe is an active wound dressing, which incorporates novel colourimetric sensor and active therapeutic processes for	Germany

		detecting and counteracting pathogenic bacteria in wounds.	
MolecuLight	MolecuLight i:X	MolecuLight i:X is a handheld device that measures the surface area of a wound and visualises the presence and distribution of fluorescent bacteria, which can contribute to earlier and more consistent detection of wounds at risk of infection.	Canada
Queens's University Belfast	Non-invasive indicator	The device is a tiny indicator that changes colour if a patient's wound shows early signs of infection.	UK
RMIT University	Magnesium hydroxide smart dressings	The dressings are multifunctional and antimicrobial which feature fluorescent sensors that glow brightly under UV light if infection starts to set in and can be used to monitor healing progress.	Australia
University of Edinburgh	MRSA detection	The device is a simple test that aims to identify MRSA in wounds which could identify the superbug quickly and help prevent infection from spreading.	UK

Funding Landscape

Our funding scan aimed to identify funding awards for the early detection and monitoring of surgical site infections and revealed 26 such projects. The majority of this funding was allocated to diagnostic MedTech innovations intended to detect SSI, as opposed to research into SSI monitoring technologies. The largest amount of funding was awarded in 2013 (£9,958,511) solely to detection technologies (**Figure 4**), while smaller, notable peaks of funding for either monitoring or detection research projects were also seen in 2010 and 2014.

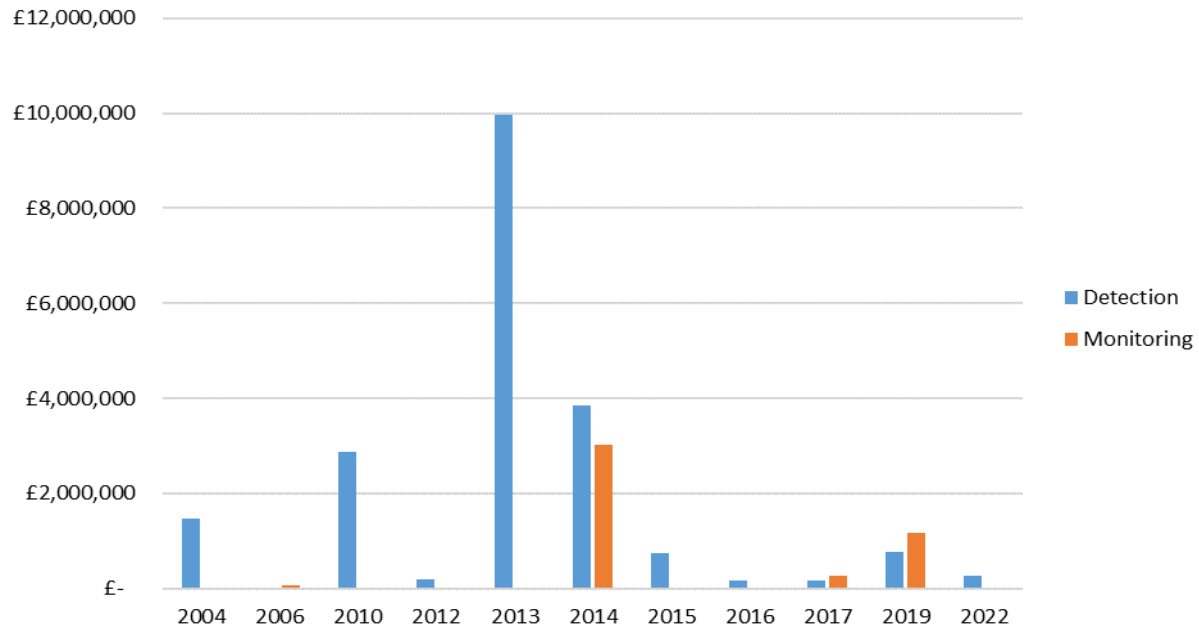

Figure 4. Global funding landscape between detection and monitoring-based technologies

The majority of identified research projects were research grants and collaborative research and development projects with a focus on the diagnosis and monitoring of infection-inducing pathogens. Internationally, the EU (56%, £18,970,925) and the UK (36%, £12,215,358) awarded the highest proportion of funding to these research projects (**Figure 5**).

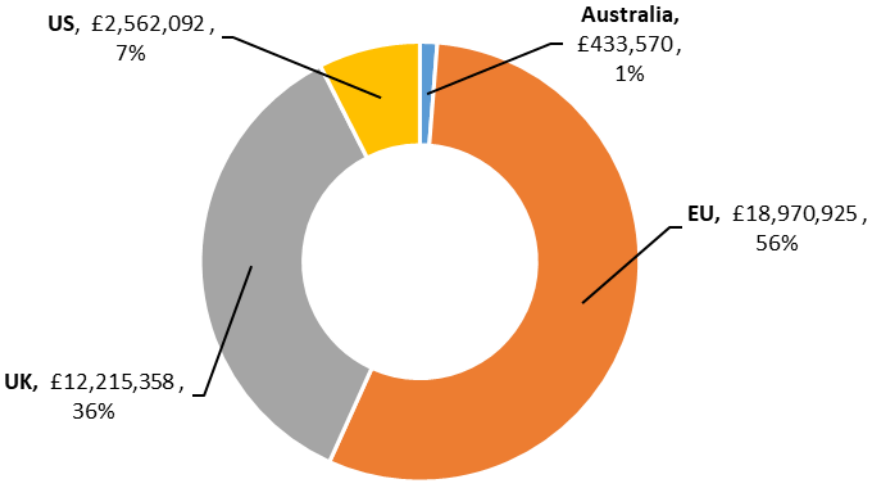

Figure 5. Doughnut chart showing the international funding landscape
Total funding identified across Australia (1%), EU (56%), UK (36%) and US (7%).

On a national scale, our scan identified 11 funded research projects awarded by multiple funding bodies. These consisted of the National Institute for Health Research (NIHR) (69%, £8,429,168), the Engineering and Physical Sciences Research Council (EPSRC) (25%, £3,027,640), and Innovate UK (6%, £758,550) (**Figure 6**).

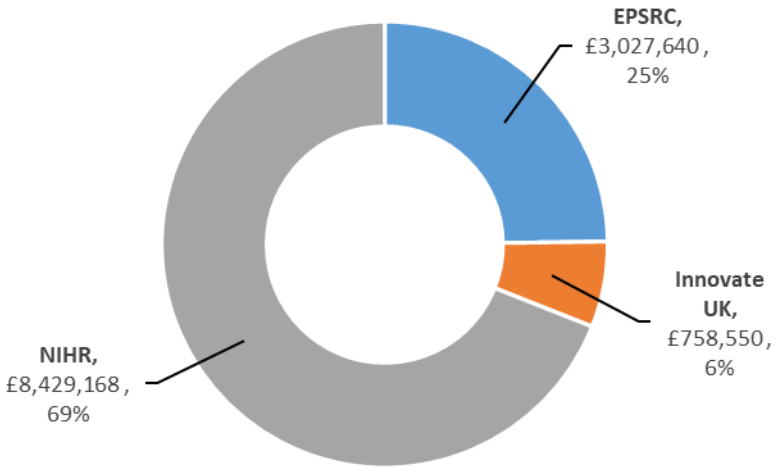

Figure 6. Doughnut chart showing the UK funding landscape
Landscape of UK funding providers with leading funders: NIHR (69%), EPSRC (25%), Innovate UK (6%).

One topic of particular note was a project by the Brentwood Biomedical Research Institute which received funding ($1,944,915) from the Congressionally Directed Medical Research Programs (CDMRP) to develop a rapid identification method for wound infection pathogens. The project looks to develop species-specific primers/probes for organisms across a variety of wound infections and to supplement those with primers/probes made from cultural isolates not previously encountered. The primers/probes will be used in a high-throughput procedure (RT-PCR) which can be applied directly to material from the wound without any need for culturing. It can be used to define the total flora of the wound within 5 hours.

The funding landscape revealed some ongoing work in biomarker detection, including an NIHR award (£1,281,526) to the National Physical Laboratory, and its collaborator Neotherix Ltd., for a novel theranostic technology (RegeniTherix). RegeniTherix comprises a material that both promotes wound healing and facilitates wound sampling and an inexpensive reader device to measure wound analytes at the bedside. As well as permitting fast, sensitive, and quantitative analysis, the technology allows for concurrent analysis of more than one biomarker. Neotherix has recently received both US and European patents for the sampling component of the ReginTherix device.

The scan also highlighted SSI detection approaches that utilised novel wound dressings. Two projects in particular, an NIHR award to the University of Manchester (£552,945) and a European Commission award to the Bacteriosafe consortium (~£3 million), made use of colourmetric sensors in a dressing. By using colour-changing microbial detectors, it is hoped that wound infections can be spotted earlier, by a patient or physician, and without the need for separate testing.

Comparisons to Other NIHR Innovation Observatory AMR Scans

It should be noted that we identified fewer technologies within the SSI detection and monitoring landscape than in our previous AMR horizons scans, which may reflect the narrow scope applied to this topic as well as the possibility of less ongoing innovation in this area. Unlike the work performed in sepsis, RTIs, and UTIs, where diagnostic tests were more prevalent and digital technologies were in a significant minority, the pipeline for SSI technologies shows a higher degree of innovation occurring in digital tech and application. This may be due, in part, to the nature of SSI detection or monitoring, in which signs of an infection may be visible at the surface of a wound, as opposed to the internal sites of infection associated with our previous scans (i.e., bloodstream, urinary tract, or lung). Similarly, although there were still a number of varying methodologies used in SSI innovations, there appeared to be less innovation using novel methods (such as microfluidics and biosensors), which could be due to a development focus on digital solutions which, at present, may not require novel laboratory methods.

Even with a search strategy designed to find detection and monitoring technologies in SSI, the majority of clinical trial results focused on SSI prevention. This may imply a greater research focus on preventative methods or techniques and aligns with the assumptions (regarding result size returns) underpinning the scope of this scan. As also seen in the overall pipeline, the clinical trials in this SSI scan featured a higher number of digital technologies or devices, as opposed to the greater amount of diagnostic tests uncovered in previous scans.

In comparison to previous AMR scans, patent numbers are considerably lower in the SSI patent landscape, however certain trends (e.g., North America, particularly the US, as a leader in patent applications; application peaks seen in 2021) still show up throughout the AMR topics. This could be due to an increase in worldwide demand for antimicrobial resistance solutions, as well as the persistence of the US as a large contributor to the MedTech market.

The majority of developers identified in this scan only have one SSI technology in development. This differed from our previous AMR scans where a greater number of developers had a portfolio of multiple technologies. BioMerieux, interestingly, has consistently shown up as key developer in each AMR scan and, as a large diagnostics company, they have a portfolio of technologies targeting a range of antimicrobial resistant organisms.

In relation to the other AMR funding landscape scans, our SSI scan yielded the smallest number of projects, though not the smallest total funds. Total funding for each topic was as follows: ~£31 million (UTI), ~£107 million (RTI), ~£124 million (sepsis), and ~£34 million (SSI). In terms of the UK funding landscape, the NIHR was the greatest contributor for both the SSI (£8,429,168) and UTI (£6,699,077) scans.

Other Innovations of Potential Interest

The scope of this SSI scan was specifically focused upon technologies intended to detect or monitor the presence of SSI, but other innovations of relevance (n = 118) were captured in the SSI dataset file (see the 'Other Innovations' tab in accompanying Excel document). The great majority of these technologies (95%) were intended for use in the prevention of SSIs, though a select few had treatment implications.

Nearly all technologies included in the Other Innovations dataset were identified as a medical device (96%), and they spanned, *inter alia*, such tools as: negative pressure wound therapy bandages, humidifiers, surgical sponges, skin closure devices, and antimicrobial sutures. Almost one-fourth of these technologies were NPWTs or NPWT support tools (27), and although the site of surgery for these innovations was rarely specified, there were specific instances of use following hip surgery or caesarean section.

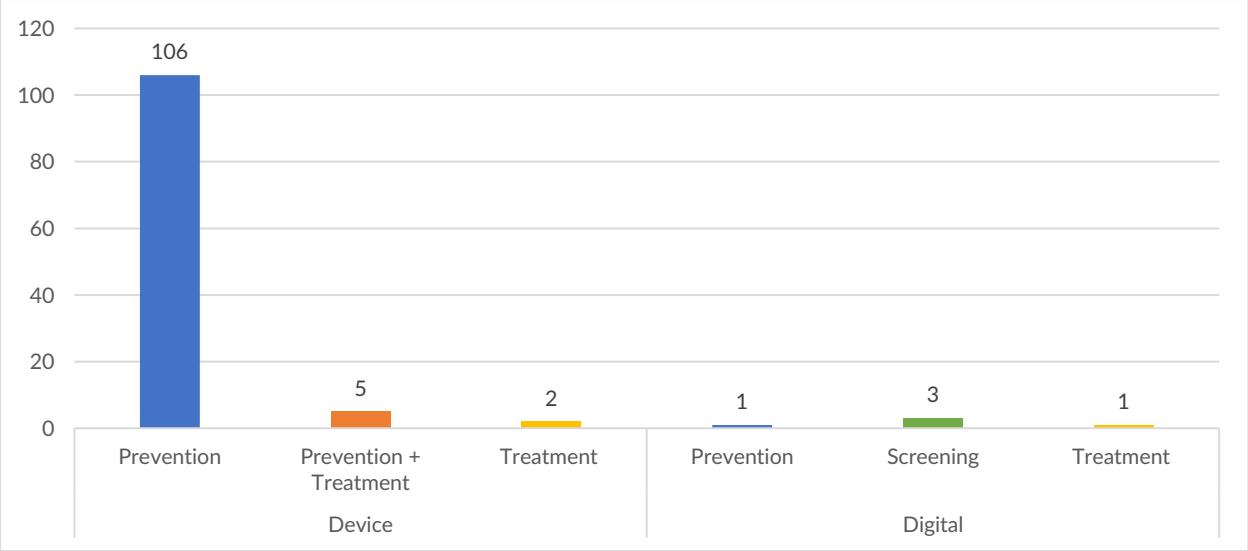

Figure 7: Division of Other Innovations by Technology Type & Place in Pathway

While there were considerably fewer digital technologies (5) intended for SSI prevention or treatment, especially when compared to the report's main dataset, those captured did present interesting applications of use. Three of the digital technologies featured SSI prediction/screening tools based on risk modelling. By identifying predictors of possible infection and anlaysing those predictors in a patient prior to, during, and post-surgery, these prediction tools hope to provide clinicians with sufficient early warning to ameliorate the likelihood of contracting an SSI. Interestingly, two of these prediction tools are under development by UK-led institutions (University Hospitals of Leicester NHS Trust and University of Oxford), and they have both received recent funding from the NIHR.

As with the primary dataset, all devices identified as an 'Other Innovation' were classified based on their stage of development (Phases 1-4), with Phases 3 and 4 indicative of late/mature stage of development. Nearly half of these technologies (49%) were in the last stage of development (i.e., Phase 4 - ready to launch/regulatory approved), and another third (34%) represented validated products (i.e., Phase 3). Overall, 45 of the 58 products in Phase 4 (mature phase) have obtained regulatory approval in 1 or more jurisdictions, with 50% of technologies in Phase 4 awarded an EU CE Mark.

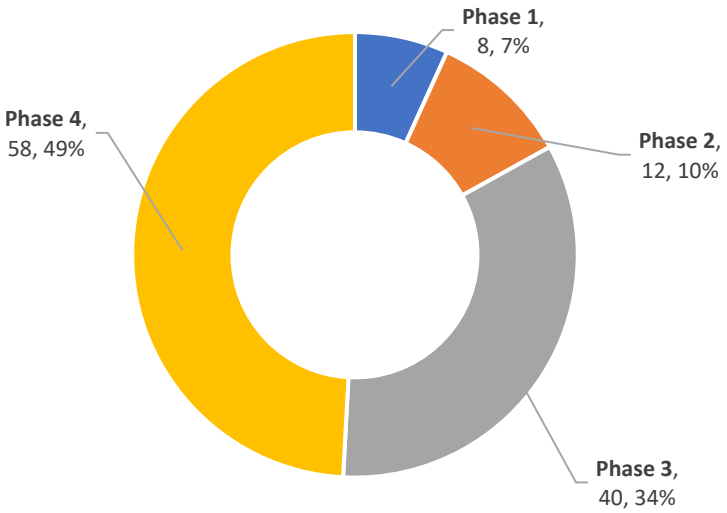

Figure 8: Doughnut chart representing the development stage of Other Innovations
In total, 118 SSI Other Innovations were identified. The technologies have been classified by stage of development: Phase 1 (i.e. concept) – 8, 7%; Phase 2 (i.e. prototype/early-stage research including preclinical studies) – 12, 10%; Phase 3 (i.e. product validated/demonstrated in relevant environment/clinical study) – 40, 34%; Phase 4 (i.e. product ready to launch/regulatory approved) - 58, 49%.

Development of these Other Innovations occurred across various organisation types, but commercial businesses appeared to be a primary driver in the area: 61 of the 118 technologies were pursued by either a company developer (56) or company collaborator (5). The American company, 3M, had the single largest portfolio of technologies and appeared as the developer or collaborator on at least 10 products. Of particular note were their own NPWT devices, as well as the Bair Hugger, a prevention tool that continuously measures a patient's core body temperature before, during, and after surgery.

Conclusion

As surgical site infections continue to represent significant burdens to patient morbidity and mortality, there is an obvious need for improved systems of detection and monitoring. This global horizon scan provides NHSE/I and the AMR Programme Board with a series of new and emerging innovations in that space. By allowing for timely detection and continuous wound monitoring, such technologies may play a key role in addressing some of the antimicrobial resistance needs associated with SSIs.

Our scan highlighted several of the research, funding, and development themes that arise when examining the overall SSI pipeline, clinical trial landscape, and funding history. Three of these particular innovation themes are included below:

1. Intended care setting for a technology and its implications of use. The largest number of technologies in this scan were intended for secondary care, which may raise evidence concerns about hospital resource, training, and fit. Moreover, remote

monitoring systems, either at home or in the community, face questions about patient data, technology updates, and appropriate patient support.

2. Purely digital technologies versus combination products. This report presents a range of technologies that includes digital applications alone, as well as digital applications + devices. Such innovations give rise to questions about approval pathways, evidence generation needs across function, and the security of patient data.

3. Role of wound dressings in SSI detection and monitoring. Though perhaps typically considered as a part of SSI prevention and/or treatment, this scan reports instances of wound dressing technology moving into a shared role of prevention/treatment + detection/monitoring. The evidence needs of each (i.e., effective therapy versus effective infection detection) may have implications for the future use of these innovations.

Overall, our scan revealed a significant number of promising innovations in the development pipeline for SSI detection and monitoring, and as presented herein, can allow members of NHSE/I and the AMR Programme Board to evaluate their potential use and impact. It should be noted that while the scope of this scan was limited to the topics of detection and monitoring, we have included other innovations, identified as part of this work, that span prevention and treatment. Future horizon scanning may be needed to further define those additional areas of interest.

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