



Original Article

PRAISE: providing a roadmap for automated infection surveillance in Europe[☆]

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ABSTRACT

Introduction: Healthcare-associated infections (HAI) are among the most common adverse events of medical care. Surveillance of HAI is a key component of successful infection prevention programmes. Conventional surveillance – manual chart review – is resource intensive and limited by concerns regarding interrater reliability. This has led to the development and use of automated surveillance (AS). Many AS systems are the product of in-house development efforts and heterogeneous in their design and methods. With this roadmap, the PRAISE network aims to provide guidance on how to move AS from the research setting to large-scale implementation, and how to ensure the delivery of surveillance data that are uniform and useful for improvement of quality of care.

Methods: The PRAISE network brings together 30 experts from ten European countries. This roadmap is based on the outcome of two workshops, teleconference meetings and review by an independent panel of international experts.

Results: This roadmap focuses on the surveillance of HAI within networks of healthcare facilities for the purpose of comparison, prevention and quality improvement initiatives. The roadmap does the following: discusses the selection of surveillance targets, different organizational and methodologic approaches and their advantages, disadvantages and risks; defines key performance requirements of AS systems and suggestions for their design; provides guidance on successful implementation and maintenance; and discusses areas of future research and training requirements for the infection prevention and related disciplines. The roadmap is supported by accompanying documents regarding the governance and information technology aspects of implementing AS.

Conclusions: Large-scale implementation of AS requires guidance and coordination within and across surveillance networks. Transitions to large-scale AS entail redevelopment of surveillance methods and their interpretation, intensive dialogue with stakeholders and the investment of considerable resources. This roadmap can be used to guide future steps towards implementation, including designing solutions for AS and practical guidance checklists. **Maaïke S.M. van Mourik, Clin Microbiol Infect 2021;27:S3**

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Introduction

Healthcare-associated infections (HAI) represent a significant disease burden in Europe and are among the most common adverse events in healthcare settings. HAI are estimated to affect 6.5% of patients in acute care hospitals on any given day [1,2]. Surveillance of HAI is a key component of successful infection prevention programmes. It provides caregivers and policy makers the necessary information to identify areas of improvement and to guide interventions. The World Health Organization considers HAI surveillance systems to be an essential component of both national and facility infection prevention and control (IPC) programmes, and it is included as one of eight core components for effective HAI prevention and control [3]. Many European countries have established regional or national surveillance networks for various infection types and various patient populations, such as those receiving care in intensive care units [4,5]. In such networks, a coordinating centre provides standardized surveillance methodology – often in line with (inter)national methods – which supports data collection, performs analysis of the reported HAI rates and, depending on the country, shares data for public reporting.

Importantly, surveillance provides information for action, and feedback regarding surveillance data should stimulate further activities to decrease HAI rates. Many local, regional and/or national level surveillance networks have demonstrated that participation and consequential increased awareness and/or targeted interventions can truly contribute to a reduction of HAI rates [6–9].

Conventional surveillance of HAI is done by manual chart review and ascertainment; this is time consuming and resource intensive [10,11]. Under the circumstances of relatively low HAI incidence in many patient groups (2–5%), the effort in performing chart review for many patients to identify only a relatively small number of patients with HAI is inefficient. In addition, conventional HAI surveillance has low interrater reliability in certain settings,

and it depends on the experience and level of training of the professionals conducting the surveillance [12–15].

These shortcomings of conventional HAI surveillance have led to the development and use of automated surveillance (AS) systems for the identification of surgical site infections (SSI), central line-associated bloodstream infection (CLABSI) or other HAI and includes both semiautomated and fully automated surveillance systems (Box 1). A 1986 pioneering report described a computer system capable of using microbiology results to identify patients with possible HAI [16]. In 2004, Trick et al. [17] first described successful automation of CLABSI surveillance. These and other AS systems rely on routine care data stored in electronic health records (EHRs) to identify patients who may have developed an infection and aim to improve efficiency and standardization of surveillance [18–20]. Although AS has the potential to facilitate data collection and has been developed and applied in the research setting within hospitals [21], there are only a few examples where it has been implemented for large-scale surveillance [22,23]. Because many of the currently available AS systems were developed in individual institutions with specific local conditions, they are heterogeneous in their design, aims and methods as well as in the definitions used. This solitary (stand-alone) development of AS systems leads to heterogeneity and poor interoperability between systems and necessitates considerable investment [24].

In order to improve efficiency of surveillance and deliver large-scale surveillance data, many hospitals, public health institutes and surveillance networks are currently investing in digital infrastructure and automation; however, guidance is lacking on how to best automate the surveillance process and ensure the delivery of surveillance data that are uniform and useful for improving the quality of care. The transition to AS entails more than converting a manual process to an automated process; it will affect surveillance targets, definitions methods and interpretation of data.

Box 1**Definitions and terminology**

Automated surveillance (AS)	Any form of surveillance where (parts of) the manual assessment are replaced by an automated process. This includes fully automated and semiautomated detection of healthcare-associated infection (HAI) and collection, validation and analysis of denominator data. AS is based on routine care data, usually by applying appropriate algorithms.
Routine care data	All data documented in an electronic format during the routine process of care (e.g. surgical procedures, prescriptions, diagnostic testing results). These data may be stored and accessed in various IT systems.
Source data	(Raw) data elements from routine care data used by algorithms to detect (possible) HAI, calculate the denominator or risk factors (e.g. microbiology results, admission and discharge dates, central line days, procedure codes).
HAI surveillance result	Individual-level HAI status data (HAI yes or no, including details of HAI) and denominator data (e.g. central line days, surgical procedures).
Observed HAI rate	Aggregate crude rate of HAI calculated based on HAI surveillance result (e.g. incidence density rate).
Locally implemented AS	AS designed and coordinated by a coordinating centre and implemented locally under the responsibility of the participating healthcare facility (Table 2).
Centrally implemented AS	AS designed, coordinated and implemented by the coordinating centre (Table 2).

With this roadmap, the PRAISE network aims to provide guidance on how to move AS from the research setting to large-scale implementation. Importantly, the aim is not to develop or validate a surveillance system as such or to develop detailed how-to checklists, but rather to offer high-level conceptual guidance for the future development of surveillance systems. Surveillance networks and hospitals can translate this roadmap to their local situation to support design and implementation of AS. The roadmap does not list all the characteristics of specific surveillance programmes but rather focuses on aspects requiring special attention in the transition to AS.

This roadmap discusses the selection of surveillance targets, different organizational and methodologic approaches to large-scale automation of surveillance and their advantages, disadvantages and risks; defines key performance requirements of AS systems and suggestions for their design; and provides guidance on how to achieve successful implementation. This document is complemented by other articles in this supplement focusing specifically on information technology (IT) and governance [25,26].

Methods

This roadmap was written by the PRAISE network (Providing a Roadmap for Automated Infection Surveillance in Europe), which is funded by the Joint Programming Initiative Antimicrobial Resistance (JPIAMR) Network Call on Surveillance (2018). This network brings together 30 experts from ten European countries working in the field of HAI surveillance (mainly northern, western and southern Europe), with the majority working in university hospitals and some in public health institutes. The network included representatives of the COMBACTE-Magnet EPI-Net network, which provides barrier-free, timely access to data on the emergence and spread of antimicrobial resistance in humans and animals (<https://epi-net.eu/>).

This roadmap is the product of two workshops, teleconference meetings and review by an independent expert panel with representatives from the European Centre for Disease Prevention and Control (ECDC), the infection prevention and control community, Eastern Europe and the United States (see the Acknowledgements). The recommendations and key points formulated in this roadmap are based on expert consensus and iterative review of the documents, and no formal assessment or methodology was used. They are meant to emphasize important aspects of AS implementation and facilitate implementation initiatives.

The project was divided into work packages that were assigned to subgroups. Each network member contributed in one or more subgroups, and a core group with representatives from each subgroup coordinated the work and monitored project progress. In the start-up workshop in March 2019, network members reviewed existing systems for automated HAI surveillance and evaluated their advantages and challenges; the outcome of this will be reported separately. In addition, essential features of (future) AS systems were discussed through several flip-over exercises. In the second workshop (February 2020), the draft roadmap and related documents were discussed and revised thereafter, also incorporating comments from the independent expert panel.

Scope and definitions

This roadmap focuses on surveillance of HAI at the regional or national levels – that is, surveillance performed by groups of healthcare facilities in a geographical region or country for the purpose of comparison, prevention and quality improvement initiatives. Coordinating centres of such surveillance networks can include surveillance centres, public health institutes or other parties appointed by participating healthcare facilities. This roadmap does not target prospective prediction of HAI risk, real-time surveillance, detection of carriage of multidrug-resistant organisms or outbreaks thereof. Because the implementation of an AS system for HAI requires considerable IT and human resources, this roadmap is likely to be applied in high-income countries first. However, as low- and middle-income countries further develop EHRs and deploy surveillance methods, this roadmap may also be a landmark for those countries and can be helpful to streamline development efforts, for example by directly incorporating elements required for AS when developing EHRs. The roadmap will use SSI and bloodstream infections (BSI) as examples throughout because these are commonly surveyed HAI and address the different challenges encountered when transferring to AS. Box 1 presents key definitions and terminology.

Targets of and approaches to AS

Box 2 provides key points regarding targets and approaches to AS.

Targets and outputs of AS

In theory, all types of HAI and specific patient populations could be targeted by AS. Each surveillance network ought to adopt and develop surveillance applicable to their setting and choose what types of HAI and what patient populations are the best candidates for AS and whether AS will completely replace manual surveillance or just be used for a selection of targets. The following criteria can help select target HAI for surveillance:

- severe (potentially life-threatening for the patient or associated with considerable burden and/or cost)
- common (the infection is observed frequently)

Box 2
Key points regarding targets and approaches to automated surveillance (AS)

- Use the most appropriate AS targets in terms of type of healthcare-associated infection (HAI) and/or patient population for your purposes and/or needs.
- Choose between semi- or fully automated surveillance on the basis of the intended use of the surveillance data, the target of AS, the case definition, stakeholder preferences and feasibility.
- Choose between centrally or locally implemented AS. Also consider existing legal regulations for surveillance or national e-health policies (if any), stakeholder preferences and feasibility in the setting where surveillance will be implemented.

- definable (there are explicit clinical criteria or surveillance case definitions)
- preventable (interventions can prevent the infection).

For AS, the following additional criteria need to be taken into account:

- accessibility (the source data required for surveillance is accessible in the participating healthcare facilities (See data sources for AS below))
- standardization (the more standardized the diagnostic and treatment practices, the more suitable the infection is for automation).

SSI and BSI are used as examples throughout this roadmap. Several groups have investigated various approaches to AS to detect SSI, with some choosing to focus on deep SSI only, given their higher severity for the patient and increased cost [27–30]. CLABSI have a high burden of disease [2], but they are relatively rare events, and their occurrence is largely limited to intensive care units and other specialized wards (e.g. oncology, nephrology) where central line use is common. Hospital-onset bacteraemia (HOB) is a quality outcome measure currently under study in the United States that will also be included as an example in this roadmap; although HOB represents all bacteraemias, not just infection, HOB rates may have a higher power to discriminate between performance in intensive care units and also include other events that are perceived as preventable, such as secondary BSI and primary BSI not related to a central line [31,32]. There is a complex relationship between targets chosen for HAI surveillance, case definitions applied and the feasibility of AS. This is

elaborated on further in the paragraphs on semi- or fully automated surveillance, risks of AS, definitions and data source.

The output of surveillance is the HAI surveillance result: patient-level HAI status and the denominator. With this, the observed HAI incidence can be calculated. In SSI surveillance, this is usually the number of SSI per 100 operated patients (or per 100 surgical procedures), whereas the output of CLABSI surveillance is most commonly the number of CLABSI per 1000 central line–days. HOB is expressed as the number of HOB per 1000 patient–days.

Semi- or fully automated surveillance

Surveillance of HAI can be automated to various degrees (Table 1), and AS in this roadmap refers to both semi- and fully automated surveillance.

In fully automated surveillance systems, all steps of surveillance – from data collection to the determination of HAI status – are performed without any human intervention or interpretation. A typical target for fully automated surveillance could be HOB or *Clostridioides difficile* infection. For other HAI, e.g. SSI, definitions need to be adapted to make fully automated HAI ascertainment feasible. As a result of these adaptations, the construct targeted by AS may subsequently change [33].

In semiautomated surveillance, the determination of HAI status is a combination of automation and chart review, for example by algorithms that retrospectively classify cases into categories of HAI probability. Low-probability patients are considered to be free from HAI, and high-probability patients undergo manual chart review to determine HAI status. Using conventional (manual) surveillance methods and accepted case definitions, patients are then classified manually as having developed or not developed a HAI [24,34]. Even though human interpretation is still required in semiautomated systems, the number of charts that require manual review is typically reduced by >65%, and for some types of SSI >95% [18,35]. Semi-automated surveillance is being used for SSI and CLABSI [29,36,37].

Both semi- and fully automated surveillance are used in current AS systems, and both are likely to increase the degree of standardization of surveillance. All patients are systematically evaluated, and the effort dependency of surveillance is reduced or absent [27,35,38–40]. The manual confirmation step in semiautomated surveillance still allows a certain degree of interrater variability, but simultaneously it also allows for nuanced clinical interpretation of the patient’s condition [24,41,42]. Because there is no manual review step to confirm infections, fully automated surveillance requires that source data be highly standardized, with respect to interpretation and completeness as well [24].

Deciding whether fully or semiautomated surveillance should be implemented depends on many factors, such as data availability, level of IT and data management support, the target of surveillance, case definitions of HAI used and stakeholder and user preferences. The choice of surveillance method should be guided by the

Table 1
Comparison of conventional, semiautomated and fully automated surveillance

Characteristic	Conventional	Semiautomated	Fully automated
Designation of HAI state	Manual chart review and data extraction	Partial automation; manual chart review for high-probability patients only	Full automation; no manual chart review
Risk of subjectivity or interrater variability	High	Medium	No
Required level of IT standardization, including clinical documentation	Minimal	Medium	High
Surveillance workload of IPC staff	High	Reduced	Reduced
IT/data management workload	Low	Increased	Increased

Abbreviations: HAI, healthcare-associated infection; IPC, infection prevention and control; IT, information technology.

surveillance's objective. The manual review step in semiautomated surveillance may promote clinicians' and IPC staff's acceptance of the surveillance result, whereas fully automated systems allow a standardized assessment of large numbers of patients and may be more suitable when data are generated for public reporting or assessment of pay-for-performance.

Centrally or locally implemented AS

This roadmap will explore two organizational approaches to large-scale AS: centrally implemented AS and locally implemented AS.

These terms refer to the level where the responsibility for the implementation of (automated) surveillance is positioned (Fig. 1, Table 2).

Within each approach, there is room for multiple solutions, and some variations will be illustrated where relevant. In the design phase, the choice between centrally and locally implemented AS must be made, as this will guide future implementation efforts. In this decision, inherent differences between the two approaches and their associated risks and advantages need to be weighted along with legal regulations or national e-health policies (if any), stakeholder preferences and an assessment of feasibility in the specific setting where AS will be implemented.

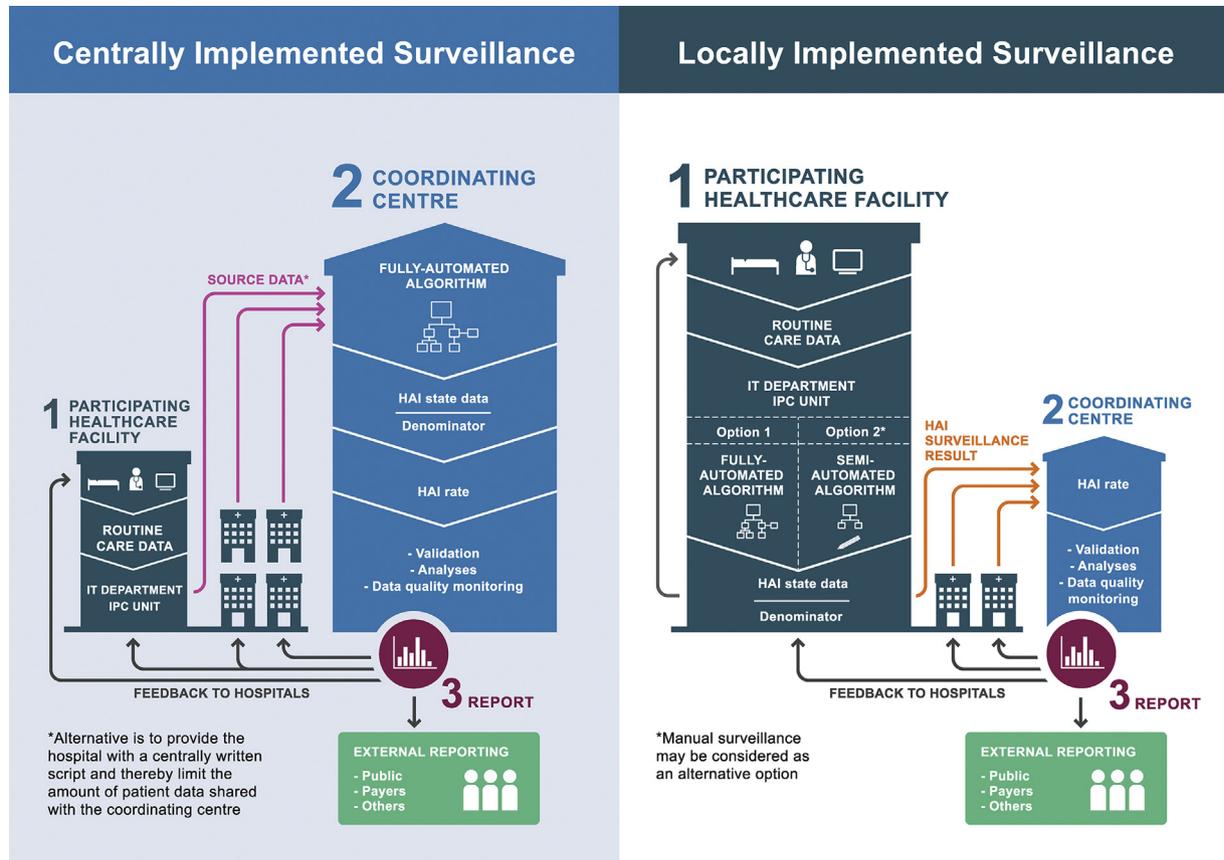


Fig. 1. Schematic representation of centrally and locally implemented AS. This roadmap focuses on surveillance within networks where a coordinating centre coordinates the surveillance efforts. Possibilities in different countries will vary depending on legislation with regard to data protection and privacy, as well as the level of digitization of health records. Abbreviations: HAI, healthcare-associated infection; IPC, infection prevention and control; IT, information technology.

Table 2
Description of centrally and locally implemented automated surveillance as used in this roadmap

Characteristic	Locally implemented AS	Centrally implemented AS
Standardized definitions of HAI	Yes	Yes
Semi- or fully automated surveillance	Semiautomated or fully automated surveillance.	Most likely fully automated surveillance.
Responsibility for the development of IT systems and algorithms	Participating healthcare facility, based on guidance from coordinating centre.	Coordinating centre, with local support; completely standardized across participating healthcare facilities.
Source data collection and the application of algorithms	Participating healthcare facility; may be outsourced to a third party.	Coordinating centre; their programmes may be implemented locally.
Validation of source data collection	Participating healthcare facility; supported by coordinating centre.	Coordinating centre, with help of participating healthcare facility.
Collection of HAI surveillance data, calculation of HAI rates and analysis of trends	Coordinating centre; participating healthcare facility may perform additional in-depth analyses.	Coordinating centre; participating healthcare facilities may also analyse their own HAI trends.
Feedback to participating healthcare facilities	Coordinating centre provides network-level feedback along with facility-level feedback.	Coordinating centre provides network-level feedback along with facility-level feedback.

Abbreviations: AS, automated surveillance; HAI, healthcare-associated infection; IT, information technology.

Importantly, in both approaches, HAI surveillance is performed within a surveillance network of participating healthcare facilities, and the responsibility of overall AS design and coordination lies with the coordinating centre. The centre plays a pivotal role in the design of the surveillance methodology, including the provision of stringent and detailed standardized case definitions and data specifications, preferably in accordance with other (inter)national protocols. Centrally implemented surveillance likely requires a more rigid governance of the partners involved, as more advanced consensus on essential elements of the surveillance methodology is needed. Centrally implemented surveillance may make AS more accessible to participating healthcare facilities that do not have the resources available to implement AS locally, and it may be easier for centrally implemented AS to obtain the required funding.

Conversely, locally implemented surveillance may offer some flexibility to participating healthcare facilities to adapt the surveillance to their local needs and resources, as long as the output meets the requirements of the coordinating centre and the quality of the surveillance is appropriately validated. This possibility for adaptation to the local situation may increase the relevance of the surveillance results for end-users (including clinicians) and possibly hospital management. It must be noted that when the surveillance network facilitates manual surveillance next to semi-automated surveillance (e.g. during the implementation phase), semiautomated surveillance is likely to have better sensitivity than manual surveillance, and comparability between both methods may be affected.

Risks of AS

As alluded to previously, the transition to AS is likely to increase surveillance capacity and reliability, but the change in methodology has several consequences that need to be explicitly considered before designing and implementing AS. These need to be communicated with stakeholders. Firstly, there is a complex relationship between the surveillance target and the definitions used. Adapting definitions will inevitably lead to changes in the target (or construct) under surveillance, and therefore interpretation of data will not be similar. This break in the data needs to be considered when comparing results to historical data and interpreting prevention studies. In addition, the development of new methods and definitions poses the risk of losing comparability among surveillance networks as they choose different approaches and methodologies for AS. This risk may be mitigated by collaboration among surveillance networks and (inter)national surveillance entities, such as the ECDC. It is also imaginable that, especially in the start-up phases, AS will run next to conventional surveillance, and these methods will produce results that cannot be compared. In addition, when AS is rolled out, research is needed to determine whether the results obtained by AS can be the driver of quality improvement [20,24].

Secondly, as with conventional HAI surveillance, the validity and reliability of surveillance will need to be carefully assessed and monitored, as automation in itself is not a guarantee of quality, and seemingly small differences in methodology can have important consequences on the results [20,43]. This applies to both the initiation phase and later phases. Measures to ensure the quality of AS will be discussed throughout the next sections of the roadmap. Finally, ongoing research is needed to optimize AS methods, to assess whether AS can contribute to reduction of HAI and to determine the best approach to implementation (see Areas of future research).

Design of AS

Box 3 lists key points regarding the design of AS.

Requirements for AS

Success in designing and implementing AS largely depends on identifying and engaging internal and external stakeholders. Balancing their needs and adapting the design of the system accordingly to obtain their commitment is key.

Table 3 delineates crucial features required of AS for it to be of value to users and other stakeholders – and ultimately to result in driving quality improvement.

Definitions

Surveillance definitions of HAI are often different to those used in clinical practice, especially when managing individual patients with infections or deciding when to initiate therapy with anti-infective agents. Epidemiologic case definitions for HAI prioritize consistency and comparability. Hence, surveillance definitions

Box 3

Key points regarding the design of automated surveillance

- Identify and involve relevant stakeholders in the design phase.
- Formulate required features of automated surveillance (AS).
- AS, in particular when fully automated, requires reconsideration of healthcare-associated infection (HAI) case definitions to address limitations in data availability and methodologic aspects of case ascertainment.
- Formulation of new HAI case definitions must take into account standardization, source data availability, length of follow-up, acceptance by infection prevention and control (IPC) staff, clinicians and hospital managers, endorsement by stakeholders, vulnerability to practice variations and comparability.
- The source data required to participate in AS should ideally be kept to a minimum; it is recommended to specify a minimum data set for participation. Performing an inventory of data availability and quality in participating healthcare facilities before designing the system is strongly recommended.
- The use of administrative data such as diagnosis and procedure codes as a sole source of data is insufficient to reliably perform HAI surveillance.
- Key criteria to select algorithms for AS include sensitivity, specificity, feasibility (with respect to data collection and methodology), clinical and IPC staff acceptance and robustness to changes in clinical practice.
- Generally, algorithms combining multiple data sources for case finding have higher sensitivity than those relying on a single indicator.
- Algorithms must be validated against the best available reference standard.
- Feedback of HAI surveillance results from the coordinating centre to participating healthcare facilities should be timely and include a flexible reporting tool that allows participating healthcare facilities to generate reports that fit their needs.

Table 3
Features required from automated surveillance

Feature	Details
Stakeholder support and endorsement by clinicians	Leadership and acceptance by IPC personnel. Surveillance of relevant events with sufficient clinician acceptance. Endorsement at all levels, both internal and external (Box 5).
Secured resources	Human and financial resources for design and production phase. Long-term commitment to guarantee continuous operation.
Sufficient number of participating healthcare facilities	Participation feasible for most healthcare facilities. Useful reference data generated.
Adequate validity and standardization of methods	Comparable HAI surveillance results (HAI status data and denominator). Central validation and aggregation of HAI surveillance results. Continuous maintenance and validation.
Flexibility in participation	Possibility for modular participation of healthcare facilities.
Data collection	Required data collection kept to a minimum, with specification of a minimum data set. Integration with national eHealth strategy (if relevant) and adherence to relevant IT standards in healthcare.
Governance and trustworthiness	Adequate validation and transparency of methods. Appropriate governance structure.
User friendliness	Interface simple to use for end users. No additional manual data entry by clinicians.
Feedback of results and reporting to clinicians	Timely and flexible generation of reports (local and central). Centrally collected data accessible for participating healthcare facilities. Correction for case mix, hospital type, device use, comorbidities and other factors whenever possible.
Reporting to the public	Standardized or stratified data reported when available. Graphical representation of results used whenever possible. Incorporates HAI data reporting requirements established by regional or national regulatory bodies or coordinating centres, as applicable.
Training	Necessary for interpreting and presenting surveillance results.

Abbreviations: HAI, healthcare-associated infection; IPC, infection prevention and control; IT, information technology.

historically have been developed to be as clear and as objective as possible; when used in different healthcare facilities or by different surveillance personnel, differences in surveillance results should be genuine and not the result of different interpretations. As a consequence, they do not include all potentially relevant clinical information [44].

When transitioning to AS, several challenges are encountered with respect to case definitions of HAI. In some cases, the source data required to apply conventional case definitions cannot be extracted in a suitable format from EHRs (in particular clinical signs and symptoms or the clinical diagnosis of HAI), or the transition to fully AS entails simplifying definitions to allow for ascertainment by algorithms (e.g. methodologic aspects). The aspects that need to be taken into account when selecting definitions for AS are listed in Box 4.

Box 4

Aspects that need to be taken into account when selecting definitions for automated surveillance

- Endorsement of healthcare-associated infection rates by clinicians and other stakeholders.
- Sufficiently clear criteria with minor subjectivity.
- Availability of source data.
- Length of follow-up and need for postdischarge surveillance.
- Vulnerability to variation in clinical practice (e.g. sampling frequency, treatment regimens) and documentation.
- Comparability across surveillance networks or over time.
- Purpose of surveillance activity (e.g. quality improvement, public reporting).

Example 1 describes two surveillance definitions for bacteraemia and bloodstream infections that are amenable to fully AS. HOB is a concept currently under study in the United States [31,32,45]. The Danish Healthcare-Associated Infections Database (HAIBA) bacteraemia definition is included in the Danish AS network [39].

Example 1. Definitions and required data elements for fully automated surveillance for bacteraemia and bloodstream infections

Hospital-onset bacteraemia (HOB): Any positive blood culture obtained >48 hours after admission until discharge, including repeat cultures and contaminants.

- Blood culture results, including date of sampling.
- Specific time interval with respect to admission and discharge.

Denominator: patient-days.

Danish Healthcare-Associated Infections Database (HAIBA) hospital-acquired bacteraemia: A positive blood culture with growth of a microorganism that is considered to be pathogenic. The sample time must fall within a period from 48 hours after the start of hospital contact to 48 hours after the end of contact. A new bacteraemia is counted if a new positive blood culture is found >30 days after the previous positive blood culture.

- Blood culture results, including date and time of sampling (also outside hospital admissions).
- Specific time interval for start and end of hospital contacts (admissions and outpatient visits).

Denominator: patient-days at risk.

In semiautomated surveillance, it is more often possible to retain conventional case definitions; the manual confirmation step allows for integration of information not available in a suitable format in EHRs and for nuanced clinical interpretation. In addition, possible HAI can be identified using proxy indicators (e.g. admission data, antimicrobial use, reoperations). Fully automated surveillance more often requires adaptation of definitions, although it may be envisioned that some adaptation to EHRs or more complicated algorithms relying on text mining and/or machine learning may address some of these challenges in the future.

Depending on the approach chosen for AS, definitions may need to be modified, and clinical information relevant for clinician's buy-in may be lost when applying AS. However, this clinical information is often subjective and not collected in a uniform matter, so this disadvantage should be balanced against the benefits of AS. When adapting HAI definitions, the aim of surveillance is crucial. In the case of using surveillance data for internal quality improvement, the endorsement of the definitions by the clinicians and IPC staff is paramount. If mandatory HAI surveillance – and (mandatory) public reporting in particular – is in place, standardization of data and comparability will be essential. Importantly, modifying the surveillance definitions often entails changing the target of surveillance (see 'Targets and outputs of AS') and the characteristics of the HAI detected; in addition, changes to definitions will preclude comparison with historical data or previous benchmarks. Finally, the effects of differences in sampling frequency (e.g. frequency of taking blood cultures) must be assessed and adjusted for because this has a major impact on rates of HAI identified.

Data sources for AS

AS, both centrally and locally implemented, requires extraction of the necessary source data from EHRs (see the accompanying IT article [25]). For the sake of feasibility, the data required to participate in AS should ideally be kept to a minimum, and it is recommended to specify a so-called minimum data set (MDS) for participation. This MDS defines the required source data in an accessible form for application of algorithms and determining HAI status, calculation of the denominator and meaningful interpretation of results (e.g. patient characteristics for case mix correction). Participating healthcare facilities can subsequently assess their eligibility for participation, prioritize their IT resources on the basis of this MDS or incorporate MDS requirements in negotiations with EHR vendors.

The exact specification of the MDS must be defined by the coordinating centre and will depend on the targeted HAI, case definitions, algorithms used and the IT resources of participating healthcare facilities. Performing an inventory of the source data availability and its quality in participating healthcare facilities before designing the system and defining the MDS is strongly recommended. Most existing AS systems rely on clinical data sources, such as admission and discharge records, culture results and antibiotic prescriptions (Table 4). In some instances, procedure and diagnosis codes assigned for the purpose of billing or epidemiology have been used for HAI surveillance, either as a complement to clinical data or as a stand-alone method. The use of such administrative data as a sole method to identify HAI – although generally easily accessible – is insufficient to reliably perform HAI surveillance [46].

Data may be stored in EHRs in a structured (e.g. admission dates, procedures, microbiology cultures) or unstructured format (e.g. narrative description of clinical signs and symptoms); the latter are more cumbersome to work with. If data are systematically documented in EHRs in a structured way and their reliability is periodically validated, the quality of the data extracted is likely to surpass the quality of manually extracted data because recording errors are eliminated [47].

Importantly, the HAI case definition chosen will ultimately dictate the requirements for the MDS. Simplified definitions relying solely on data commonly available in a structured format may facilitate fully automated surveillance. The required source data must then be available in all participating healthcare facilities and documented in a similar fashion. Collection of data on clinical signs and symptoms or judgement regarding the source of infection may not be feasible when relying on structured EHRs data [33]. Some AS systems use natural language processing or text mining to transform free text into structured information [48–50]. However, developing natural language processing algorithms requires considerable investments – possibly local for each hospital – and relies on adequate clinical documentation. The added value of incorporating this technology in addition to the use of structured data has not yet been firmly established [51–54].

With respect to postdischarge surveillance, if patients seek care at the hospital where the initial surgery was performed, SSI will likely be picked up if data collection is extended to include this time period and includes outpatient care. This postdischarge surveillance may be complemented by (electronic) patient self-reporting, for example using smartphone applications [55] or – if data

Table 4
Suggested MDS for semiautomated surveillance of deep and organ/space SSI and BSI

Characteristic	Infection targeted		Location of data ^a	Quality of data
	SSI	BSI		
Denominator data				
Surgical procedures	MDS	—	A	Generally good
Admission/discharge dates, at unit and hospital level	MDS	MDS	A	Generally good
Device use	—	MDS (CLABSI)	C	Not well determined
HAI state data				
Microbiology culture results	MDS	MDS	L	Generally good ^b
Antimicrobial use	Optional	Optional	C/P	Generally good ^b
Surgical procedures	MDS	—	A/C	Generally good
Radiologic interventions	Optional	—	A/C	Not well determined
(Re)admission/discharge	MDS	—	A/C	Generally good
Patient self-reporting (ambulatory/digital app)	Optional	Optional	C	Generally good

Abbreviations: BSI, bloodstream infection; CLABSI, central line-associated bloodstream infection; HAI, healthcare-associated infection; MDS, minimum data set; SSI, surgical site infection.

^a Where data can be found/extracted can vary by hospital. Data locations are as follows: A, administrative database; C, clinical notes; L, laboratory information systems; P, pharmacy systems.

^b Data are generally reliable, but formatting may differ.

Table 5
Features to consider when selecting an automated surveillance (AS) algorithm

Characteristic	Locally implemented AS	Centrally implemented AS
Feasibility of source data collection	Ideally feasible in all hospitals where it will be used. Participating healthcare facilities can adapt data collection to their setting, albeit with adequate validation and to a degree agreed with the coordinating centre.	Must be feasible in all hospitals where it will be used.
Complexity, methodology, maintenance and technical feasibility	Implemented in participating healthcare facilities. Methodological feasibility is paramount.	Implemented at coordinating centre or provided in script to hospital. More room for complex models.
Clinical interpretability and acceptance	Method should be understood and accepted by end users and stakeholders. If semiautomated, manual confirmation may improve clinical acceptance.	Method should be understood and accepted by end users and stakeholders. Black box systems may limit interpretability and acceptance.
Robustness to differences or changes in clinical practices (e.g. diagnostic frequency)	Interpretability and comparison over time or across hospitals. If semiautomated, sensitivity should be maintained; small losses in specificity can be corrected by manual confirmation.	Interpretability and comparison over time or across hospitals.
Performance characteristics	Meets prespecified criteria for sensitivity and specificity.	Meets prespecified criteria for sensitivity and specificity.
Vulnerability to (inadvertent) manipulation	Especially in setting of public reporting or pay for performance.	Especially in setting of public reporting or pay for performance.

protection regulations allow – by linking clinical or administrative data (such as readmissions) across healthcare providers. In centrally implemented surveillance, records could be matched on a higher level to allow for data collection from other sources, including data from ambulatory and primary care, other hospitals, billing records or other databases [56].

What data on case mix or risk factors should be considered mandatory for participation depends on striking a careful balance between collecting the required information and maintaining feasibility. The importance of risk adjustment will also depend on the intended use of surveillance data. In particular, in a setting of public reporting or pay-for-performance analyses, collection of reliable data on risk factors will be paramount.

Algorithm selection and design aspects

Because the exact details of algorithm development are constantly evolving, this roadmap will not provide detailed technical guidance on how to design algorithms but instead highlights characteristics to consider when selecting or designing an algorithm (Table 5). The accompanying IT article addresses some technical aspects of algorithm implementation ([25] See ‘Surveillance algorithms’).

Generally, algorithms combining multiple data sources for case finding have higher sensitivity than those relying on a single indicator, until a point of saturation is reached [18,57,58]. Importantly, models relying solely on microbiologic culture results or mandating a positive microbiology culture may lead to both under- and over-detection of SSI because positive cultures are not always a prerequisite for SSI diagnosis, and conversely because a positive microbiology result does not always reflect the presence of an infection [59]. Ideally, algorithms are defined such that they align with clinical practice and do not lose their sensitivity with minor modification in clinical practices [29]. Especially in the setting of mandatory reporting or financial consequences, the vulnerability of the algorithm – or any method of surveillance – to (inadvertent) manipulation needs to be considered.

Most AS systems, both semi- and fully automated, rely on classification algorithms to determine HAI state [18,27,39,60–62].

Example 2 provides an example of a simple algorithm that can be considered for semiautomated surveillance [27,29].

Example 2. Semiautomated surveillance algorithm for deep surgical site infection after hip/knee arthroplasty and determinants of success

Classification algorithm

Patients are included in the surveillance on the basis of procedure codes.

All patients who meet three of the following criteria within 120 days after surgery should undergo manual chart review; all others are considered free of surgical site infection.

- Microbiologic culture from relevant body site (e.g. tissue, blood): positive culture, regardless of species, or five or more cultures taken from relevant body site.
- Reoperation by initial specialty (e.g. orthopaedics).
- Fourteen days or more (cumulative) of antimicrobial prescribed, including outpatient.
- Initial length of stay >14 days or readmission to initial specialty.

Determinants of success

- Check agreement of algorithm against actual clinical practice in participating healthcare facility.
- Avoid overly specific criteria in order to increase robustness to changes in clinical or coding practices (e.g. reliance on specific antibiotics or specific procedure codes).
- Combine multiple criteria for case finding to improve sensitivity.
- Perform yearly maintenance of the selection of procedure codes to include in the surveillance.
- Develop a method to account for multiple procedures during one surgery and to perform validation of the procedure inclusion process.

An alternative but less commonly applied approach is the use of multivariable regression models that apply a weighted regression formula to estimate the probability of having had an infection [63,64]. Expanding on classical multivariable regression, fuzzy logic, machine learning and artificial intelligence techniques are increasingly applied to detect possible cases of HAI [65–67]. These more sophisticated techniques generally achieve higher specificities at similar sensitivities; however, the complexity of the methodology may preclude a simple and straightforward understanding of the classification by clinicians and IPC staff. Future research will need to demonstrate the performance of artificial intelligence and machine learning technologies for AS and determine their most useful utilization. Application of algorithms, both simple and complex, requires specialized expertise and may increase the need for data management and statistical support within both coordinating centres and participating healthcare facilities (See ‘Commitment and resources’).

Before accepting algorithms for use, their performance must be assessed with respect to identifying HAI and quantifying the denominator (See ‘Validation of AS’). The performance of AS systems is often related to surveillance by conventional methods. Hence, any assessment of system performance will also depend on the quality of this reference standard. When evaluating semiautomated surveillance, the outcomes can be compared to conventional surveillance (i.e. surveillance that is based on manual chart review). Generally, cases identified as high probability are compared to the manual reference standard. On the basis of the literature, a sensitivity of 90% is achievable for most HAI and should be considered the minimal performance level in semiautomated surveillance [68,69]. The positive predictive value (PPV) of the algorithm mainly reflects the efficiency of the screening process and will also depend on the incidence of the targeted HAI; a minimal performance cannot be given. The acceptable value will depend on the requirements set by users. In fully automated surveillance, there is usually a trade-off between sensitivity and specificity. Depending on the targeted application and objective of surveillance, the end users and stakeholders must choose what outcome measure is prioritized, sensitivity or specificity and PPV. It can be argued that confidence in events detected being true cases is better than identifying all possible cases. These considerations will define acceptance criteria for AS.

In contrast, when definitions are altered in order to accommodate AS, a head-to-head comparison to reference data collected through conventional surveillance may not be informative enough because both definitions may target different entities. Besides comparing algorithm performance to the best available reference standard, analyses may be complemented with other outcomes to assess the usefulness of the events detected, such as mortality, length of stay or an association with cost.

Feedback and reporting of outcomes

In order to drive quality improvement cycles, timely feedback of surveillance results from the coordinating centre to the participating healthcare facilities is paramount [3]. Depending on the country's policies and legal regulations on HAI surveillance, this may be feedback of aggregated results only, confidential feedback to the participating healthcare facilities with a comparison of the hospitals' HAI rates to aggregated rates from comparable hospitals, or results may be made available to the general public or payers [70].

Feedback of HAI surveillance results from the coordinating centre to participating healthcare facilities may be facilitated by

using a digital environment with a flexible reporting tool that allows participating healthcare facilities to generate reports that fit their needs, both in centrally and locally implemented surveillance (See ‘User interfaces’ and ‘Secure data transfer’ in [25]). Ideally, hospitals receive their crude HAI rate and a rate adjusted for available risk factors, including a visual presentation of data through an (interactive) dashboard. In the case of centrally implemented AS – where the HAI surveillance result is determined in the coordinating centre – feedback of the patient-level HAI surveillance result and line listings should be organized in compliance with privacy regulations. In addition, AS may lead to a more timely feedback of rates and comparison to reference data, and reports may be accompanied clear steps to be taken using the data (goal setting, action planning), thus promoting the use of data in quality improvement programmes. Next to providing feedback, the coordinating centre is in a position to analyse the HAI surveillance results in order to detect trends and outbreaks and to notify participating healthcare facilities. Given the large amounts of data that may be collected, this will require the development of dedicated methods. This carries a responsibility that should be addressed in the design phase and requires adequate resources and governance.

Providing a secure environment for feedback and differentiating the reporting for different audiences (hospitals, payers, public) can be helpful to provide all stakeholders with the information relevant to them.

Implementation of AS

Box 6 lists key points to achieve successful AS implementation.

Commitment and resources

An array of published articles point to the fact that although AS systems exist and have been validated in the academic literature, their adoption is still limited [71]. Data suggest that in hospitals with strong leadership, organizational support and engagement with patient safety, those involved in surveillance feel more supported in implementing such systems and overcoming barriers, leading to greater satisfaction with AS [71]. Successful organization, implementation and maintenance of AS first and foremost requires a clear definition of the purpose of surveillance and commitment from relevant stakeholders (Box 5), both at the level of the coordinating centre and the participating healthcare facility. This includes establishing the political and scientific background through alignment with national e-health strategies, consultation with professional organizations and relevant national societies as well as creating support locally among hospital management, clinicians, infection control and IT staff. In addition, cultivating an institutional culture that embraces technology and views change positively is also likely to improve data quality [72]. Clear communication of the potential benefits for clinicians and patient outcomes may help create support and the involvement of clinicians in all steps of implementation may further increase the quality and impact of surveillance. Governance aspects of stakeholder involvement appear in the governance document ([26] See “Engaging with participating healthcare facilities”). Additionally, adoption of AS should also include training of staff regarding the methodology and the interpretation of data for useful feedback and quality improvement. This training should also be incorporated in professional training programmes (Appendix A) [71].

Development and implementation of AS will require a considerable investment of resources. Coordinating centres should secure long-term funding for establishing and maintaining the system. Adoption of AS also requires substantial investment from participating healthcare facilities to implement AS within their IPC departments and to modify and maintain IT systems and for training of personnel. These needs should be addressed at the outset of implementation projects. Implementation of AS will likely result in a reduction of human resources needed to perform surveillance through chart review, but importantly, it will ask for investment of different skills to implement and operate the system. For example, strengthening the availability of epidemiologic, IT and statistical support in IPC departments will be important. Resources also need to be secured for maintenance and ongoing improvements to the systems. Despite these investments, the transition to AS is expected to free up IPC personnel, and resources may be refocused on prevention efforts within the organization, although the achieved benefits have not been formally quantified to date.

Box 5

Potential stakeholders in (automated) HAI surveillance

Participating healthcare facilities:

- Infection prevention and control personnel, including clinical microbiology, infectious disease or hospital epidemiologists, and, if applicable, clinical pharmacists.
- Clinicians (doctors, nurses, other healthcare workers). Hospital management, including patient safety and risk management.
- Hospital information technology (IT).
- Data protection officer, legal department and ethical committee.

Coordinating centre:

- Surveillance network management.
- IT and data protection officers (including ethical committee).
- Public health institutes and other related scientific institutes.

Community/society:

- Patients, patient groups and, if applicable, the general public.

Government agencies and other relevant bodies in healthcare:

- Ministry of health (or equivalent).
- Regional and national public health authorities.
- Insurers and other payers.
- Data protection agency.
- Relevant professional societies.

Potential third parties:

- Independent IT companies and IT service providers.

European and other international partners:

- European Commission.
- European Centre for Disease Prevention and Control (ECDC).
- World Health Organization (WHO).

Box 6

Key points to achieve successful automated surveillance implementation

- Successful organization, implementation and maintenance of automated surveillance (AS) requires commitment from relevant stakeholders.
- The purpose of surveillance should be clearly defined.
- An implementation strategy should include the training of participants regarding methodology and interpretation of data ([Appendix A](#)).
- Long-term funding must be secured to cover costs of AS development and operation, both at the level of the coordinating and participating healthcare facilities.
- Implementation and operation of AS will require different skills than conventional surveillance, and training should be included in professional training programmes.
- Responsibilities should be assigned to each relevant party at the start of implementation ([Table 6](#)).
- IT development should comply with current technical and data protection standards with regard to interoperability, data storage and sharing.
- Allow for sufficient piloting and phased development, which are crucial for successful implementation. Modular participation and flexibility are probably crucial in order to achieve successful large-scale adoption.
- Develop an adequate governance structure to encourage transparency and accountability for all stakeholders.
- For endorsement of the surveillance network by stakeholders, including the public, transparency regarding the purpose, data collection, data handling and validation is essential.
- Involve legal specialists and data protection officers who understand the purpose of AS from the start of development to ensure adequate governance of data access and sharing.
- Implement changes in legal regulations relevant for healthcare-associated infection surveillance, as necessary.
- Performance of AS can vary across different clinical settings and patient populations; it should undergo clinical and technical validation in all contexts where it will be used, at initiation and then periodically after implementation.
- Specifically for semiautomated surveillance, ensure adequate validation of the manual ascertainment, as is currently also performed in conventional HAI surveillance. This remains essential.
- Securing sufficient resources for maintaining and adapting the system is paramount, including epidemiologic and IT support in the coordinating centres and in participating healthcare facilities.
- Throughout implementation, it is recommended that the coordinating centre and participating healthcare facilities evaluate whether the surveillance system provides meaningful data.

Table 6
Tasks and responsibilities that must be covered in AS, including assignment to specific roles

Task or responsibility	Role	Details	Coordinating centre	Participating healthcare facility
Resourcing, corporate governance and organizational buy-in	Senior management	Secure long-term commitment and funding for AS. Enforce adherence to surveillance protocol and data and privacy regulations.	✓	✓
Clinical leadership IT strategy	Medical director IT manager	Promote clinician buy-in of surveillance results. Ensure appropriate (human) resourcing and infrastructure. Support adherence to IT standardization and interoperability initiatives.	✓ ✓	✓ ✓
Compliance with data protection regulations	Data protection officer, chief information officer	Ensure privacy and public benefit requirements are met for any personal identifiable information collected. Optimize technical and organizational measures for data protection.	✓	✓
Central coordination	Surveillance network management	Specify definitions, systems, design, quality monitoring (including validation), communication, training.	✓	
Local coordination	IPC lead and team	Coordinate and specify of local surveillance systems, design and validation. Communicate with (local) IT and coordinating centre. Perform manual review of selected patients' charts if needed.		✓
Consent or accept use of data (if applicable)	Patients	If applicable under current European and national legislation. Optional: collect data after discharge.		✓
Documentation in EHRs Management of local IT infrastructure	Medical and nursing staff Local IT staff and lead, in IPC and hospital wide	Document routine care data as part of daily workflow. Build and maintain EHRs modifications and facilitate data extraction. Perform version management of technical specification.		✓ ✓
Data management Analysis and feedback of HAI data and rates	Data manager Analysts, epidemiologists, IPC specialists	Perform data extraction and apply algorithms. Analyse trends and provide benchmarking information. Detect clusters of HAI. Generate reports for reporting and local use.	✓ ✓	✓ ✓
Use of HAI rates to guide quality improvement	IPC, clinicians, quality improvement team	Interpret outputs and close the surveillance loop, driving improvement. Provide feedback regarding surveillance targets.		✓

Abbreviations: AS, automated surveillance; EHRs, electronic health records; HAI, healthcare-associated infection; IPC, infection prevention and control; IT, information technology.

Organization of roles and responsibilities

When implementing (automated) surveillance systems, responsibilities should be assigned to each relevant party. [Table 6](#) details the suggested roles and responsibilities at the level of the coordinating and participating healthcare facility. [Appendix B](#) contains a more detailed description of all potential stakeholders and their roles and responsibilities; see also the governance article [26]. The exact professional profile most suitable for each task can be defined according to the local situation.

Development and implementation strategies for AS

As mentioned above, AS can be approached from a central or local perspective, with each approach having specific features, advantages and limitations (See 'Centrally or locally implemented AS'). When moving towards large-scale AS, allowing for sufficient piloting and phased development is crucial in order to achieve successful large-scale adoption. Modular participation and flexibility will likely contribute to successful implementation. Importantly, implementation challenges may vary substantially between countries as a result of differences in organization of the healthcare system, history, extent and the methodology of existing HAI surveillance, political interest in this subject, resources available and existing regulations (e.g. data protection).

The 'minimum viable product' concept may be useful in staging development. This concept focuses on first delivering a product with just enough features to satisfy early adopters and provide feedback for future improvement. Developing a product with more features before initial adoption tends to increase costs and risks – for example, as a result of incorrect assumption or unforeseen

incompatibilities [73]. Conversely, when staging development, choices are ideally made such that resources are used efficiently, and expansions or upgrades do not require extensive redevelopment and reinvestment of already existing parts. Further systems should be designed such that they require the least reprogramming if other systems such as the EHRs or administrative systems were to be replaced. In addition, there should remain sufficient incentives to upgrade systems or expand participation to allow for additional modules. Implementation of AS may benefit from codevelopment with other automated systems for quality improvement, for example surveillance of other, noninfectious or adverse events. The

Box 7

Phasing in automated surveillance

Example	Aspect suitable for phasing
No. of participating healthcare facilities HAI targeted by AS	Start with a small number of pilot hospitals. Start with surveillance of a few and technically straightforward HAI; allow for optional addition of other types of HAI.
Data sources	In semiautomated surveillance, start with simple algorithms that can be refined based on data availability.
Algorithm complexity	Techniques can be upgraded based on resources in participating healthcare facilities.
Risk factor data	Start with fewer risk factors, then expand based on data availability.

IT article describes a minimal viable product for surveillance of HOB as an illustrative example ([25] Fig. 2).

Development of large-scale AS can be phased in various ways, both in locally and centrally implemented surveillance, thereby providing flexibility to the participating healthcare facility and/or the coordinating centre to implement AS, as shown in Box 7.

Aside from these possible phases in development, a range of approaches to communication infrastructure is available to implement both centrally and locally implemented AS, and detailed scenarios can be found in the IT article ([25] ‘communication between participating hospital and coordinating centre.’). For instance, centrally implemented AS can either entail applying the algorithm within the coordinating centre on source data provided by healthcare facilities, or the coordinating centre can provide a programming script for the standardized algorithms that healthcare facilities can run locally on source data and subsequently send the HAI result sets to the coordinating centre. This latter approach will, however, require careful version management to guarantee comparability across healthcare facilities. In locally implemented AS, source data collection and the application of algorithms could be supported by the coordinating centre providing algorithms and methods to participating healthcare facilities. Alternatively, analyses may be outsourced to a third party (under the responsibility of the participating healthcare facilities) if there are insufficient local resources to implement and maintain systems. In all scenarios, detailed technical specifications are crucial; small differences in implementation can have serious consequences on the events detected [43]. The IT requirements for AS should be incorporated in organizations’ commitment to IT, and strategies for IT both nationally and locally and all IT developments should comply with current technical and data protection standards with regard to interoperability, data storage and sharing and infrastructure design ([25], ‘Standardization and Interoperability’).

Example 3 describes experiences obtained from the implementation of the Swedish Infection Tool. This tool collects indications for antibiotic prescriptions to detect all types of HAI and has been implemented nationally in Sweden.

Example 3. Experiences from early phases of implementation of the Swedish infection tool

1. Committed hospital managers and IPC professionals who accept responsibility are facilitators to implementing AS.

2. An implementation group of people needs capacity and competence in the following areas:

- Project leadership.
- Competence in local working processes for diagnosing and managing infections.
- Competence in the use of EHRs locally.
- Communication and education planning for reaching out.
- Technical implementation needs of the system.
- Documentation of IT infrastructure built to ensure correct labels of places, persons and data types.
- IPC competence to ensure the data generated are meaningful for HAI prevention.

3. Important early tasks

- Keep an updated list of persons involved and responsible.
- Conduct a risk analysis for the implementation project.
- Develop a long-term plan for implementation, system development and securing future funding; this can

prevent too slow a pace for implementing important upgrades and declining commitment as funding ceases.

- Data validation to ensure data acceptance among clinical end users.
- Build competence at clinic level in using the data feedback system to retrieve relevant data for local improvement programmes.

Abbreviations: AS, automated surveillance; EHRs, electronic health records; HAI, healthcare-associated infection; IPC, infection prevention and control; IT, information technology.

Privacy, data security and public trust

Data safety and responsible data sharing are pivotal for (personalized) medical data. Thus, the development and implementation of large-scale AS will require specific attention to data privacy, data security and maintaining public trust. The design of systems should be compliant with international, national and local regulations, such as the General Data Protection Regulation (GDPR), national laws and specifications as well as local policies of participating healthcare facilities. The implications of the GDPR and the possibilities to analyse personal and/or medical data depend on the purpose of surveillance. In many situations, the explicit consent given by the data subject for a specified purpose is required in order to share personal health data, although there are exemptions for specific situations. The possibilities are also dependent on national laws that may provide exemptions or more specific interpretations of the regulation; hence, implications may differ from one country to another. It is expected that the implication of the GDPR and local regulations on the possibilities to perform surveillance for quality improvement and public health purposes will be clarified over the coming years. Because of this complexity, early involvement of legal specialists and data protection officers who understand the aims that are pursued by the surveillance network regarding AS is strongly recommended. As described earlier, there are multiple possible designs for AS, with differences in the extent of data sharing, level of aggregation and possibility for anonymization; in addition, the choice for a design may be guided in part by the possibilities available under relevant legislation.

Aside from complying with relevant regulations and technical standards, the importance of pursuing trustworthiness from the perception of the public as well as from participating healthcare facilities cannot be emphasized enough. This should also include a reflection on the ethical aspects of reusing medical data – fully anonymized or not – for the purpose of surveillance healthcare improvement. To ensure both confidence in adequate and confidential data handling and trust in the surveillance results, adequate communication and transparency with regard to the purpose of data collection, data access and sharing are important. Achieving acceptance of the surveillance results requires monitoring, auditing and validating methods and ensuring transparency. Further reading on public trust, transparency, data protection and resources regarding responsible data sharing can be found in the accompanying Governance article ([26]). Technical aspects of data sharing and security are discussed in the IT article ([25] ‘Secured data transfer’).

Validation of AS

Performance of AS can vary across different clinical settings and patient populations, and it should undergo clinical and technical validation in all contexts, where it will be used at initiation, periodically after implementation and also when indicated as new

Table 7
Validation requirements, at initiation and periodically, with examples

Characteristic	At initiation	Periodically (yearly)
Correct extraction of source data	Develop automated programming scripts to check for inconsistencies; outlier handling, technical validation. Manual verification of completeness by random sampling.	Random sampling of data elements for manual verification.
Algorithm application	Assessment of completeness of coding systems (e.g. inclusion of relevant microbiologic results or antibiotics). Programming errors.	Monitor for changes in coding systems or IT updates.
Algorithm performance	Assessment of algorithm to correctly identify patients with HAI (compare to reference standard). Agreement with clinical and documentation practices.	Manual validation of a random or targeted sample. Audit of changes in clinical practice.
Denominator calculation	Correct application of inclusion and exclusion criteria (compared to references). Calculation of device-days.	Manual validation.
Data sharing with (and analysis by) coordinating centre	Assessment integrity and completeness of data sent to coordinating centre.	Periodic manual check of data integrity and completeness.
Clinical acceptance	Discussion with clinicians. Association with other outcomes, if deemed relevant.	Periodic discussion with clinicians. Associations with other outcomes.

Unless stated otherwise, these validation requirements apply to both locally and centrally implemented surveillance. Abbreviations: HAI, healthcare-associated infection; IT, information technology.

systems are adopted. This includes validation of the source data, algorithms, denominator data and an assessment of the ability to provide reliable benchmark data. Table 7 delineates elements requiring validation; these apply both to locally and centrally implemented surveillance, although the responsibility for the different tasks may be implemented differently in each approach.

Validation of the source data includes technical validation to assess completeness and inconsistencies ([25] 'Technical data validation') as well as clinical validation to assess whether the correct data have been extracted and whether the data are incorporated correctly in algorithms.

The performance of an algorithm is generally validated against a reference standard; for example, conventional HAI surveillance is based on manual chart review. Ideally, all diagnostic accuracy markers derived from a 2×2 contingency table (sensitivity, specificity, PPV and negative predictive value) should be assessed using a study design that avoids differential and partial verification bias [74,75]. Overall accuracy is the ratio of all true predictions over all predictions being made, but this is only useful if there are balanced numbers of samples belonging to each group (HAI vs no HAI), and the use of accuracy as a performance measure should usually be avoided. The *F* score is the harmonic mean between sensitivity and PPV, but it can be misleading and is not a sufficient measure for assessing algorithm performance [76,77].

In some cases, there is insufficient reference data available to allow for analysis of a 2×2 table, thus precluding a formal assessment of sensitivity. For the sake of efficiency, some validation studies then only consider the PPV as a marker of performance. However, this approach is not recommended because it leaves users uninformed regarding the true incidence of infections; further, the sensitivity cannot be estimated because cases not detected remain unrecorded. Alternative solutions to this challenge include randomly sampling patients classified as high or low probability (HAI/no HAI) with inverse probability weighting; or applying a secondary reference standard to patients for whom there is no reference standard available [74].

Similar to reliably identifying the target HAI, a reliable assessment of the denominator data is paramount in order to obtain comparable HAI incidence rates, both in locally and centrally implemented surveillance. Whether deviations from manual

assessment are acceptable will depend on the magnitude of the error and the consequences for interpretation on the local and network level. Importantly, manual counts of denominator data can also contain errors, so a balanced assessment of acceptability is warranted [47]. Particular aspects of denominator calculation that can be difficult to automate include use of intravenous catheters or other devices, as documentation can be poor and data are not always captured in a structured manner. Other challenges include selection of the correct surgical procedure and application of exclusion criteria (e.g. primary/nonprimary procedures and identification of preexisting infections) [47].

In both locally and centrally implemented AS, the coordinating centre can facilitate appropriate validation by sharing validation protocols, organizing top-down validation or peer-to-peer audits. Specifically for semiautomated surveillance, ensuring adequate validation of the case ascertainment by manual chart review – as is currently also performed in conventional HAI surveillance – remains essential.

Maintenance of the system

An established AS system needs ongoing maintenance and further development activities, both in the participating healthcare facilities and in the coordinating centre, in order to maintain data quality and ensure acceptance of the system [20]. This requires the allocation of sufficient resources. Depending on the number of participating healthcare facilities and the number of HAI targeted, the responsible team at the coordinating centre needs to include at least one epidemiologist and at least one IT expert, although it may also include other professionals such as microbiologists, IPC professionals, pharmacologists or IT architects. In addition, superusers may be appointed in local hospitals to validate data and perform first-line troubleshooting. Resources should also be allocated for the maintenance of servers, software licences and legal support. Essential tasks that require ongoing maintenance are listed in Table 8 [25].

Finally, throughout implementation, it is recommended that the coordinating centre and participating healthcare facilities evaluate whether the surveillance system provides meaningful data (e.g. accurate, discriminating hospitals with good and bad

Table 8

Tasks to perform during the maintenance phase of AS operation

Task during maintenance phase	Coordinating centre	Participating healthcare facility
Maintain contact with relevant (clinical) stakeholders	✓	✓
Train data users (including health authorities) to avoid misleading conclusions	✓	
Change management: Adapt to changes in clinical practice, stakeholder preferences or legislation	✓	✓
IT governance: Adapt to changes in EHRs, hospital IT systems or IT standards (including interoperability and security)	✓	✓
Coordinate improvements	✓	
Perform and/or support validation of source data collection and algorithms	✓	✓
Keep governance and legal issues up to date	✓	✓
Offer IT support to participating healthcare facilities (incident management)	✓	
Offer epidemiologic support to participating facilities	✓	
Train new staff in participating healthcare facilities	✓	✓

Abbreviations: AS, automated surveillance; EHRs, electronic health records; IT, information technology.

Table 9

Areas of future research

Topic	Examples
Definitions and metrics	Research into new case definitions suitable for AS. Assess the acceptability of case definitions or surveillance targets.
Algorithms, denominator and risk adjustment	Algorithms, also for use in specific settings (e.g. HAI associated with short admissions or specific patient populations). Value of machine learning and artificial intelligence. Value of specific data sources in AS. Comparability between methods (manual or automated) and over time. Methods for computing or estimating the denominator. Methods of risk adjustment for new metrics.
Implementation aspects	Strategies for successful deployment (e.g. top-down or bottom-up). Definition of minimum viable products and minimum IT standards.
Impact assessment	Acceptance of HAI rates generated by different AS methods by stakeholders, including healthcare providers and patients. Assessment of the efficacy of data generated by AS in reducing HAI rates or other outcome measures (length of stay, mortality). Assessment of the feedback process to guide change.
Cost–benefit assessment	Opportunities to use the outcome of AS for other purposes (e.g. research). Workload reduction achieved by AS and changes in human resources required. Cost–benefit assessment of automated surveillance compared to conventional surveillance.

Abbreviations: AS, automated surveillance; HAI, healthcare-associated infection.

performance), including an ongoing evaluation of the ability of data to drive improvement. Depending on the number of participants, this assessment could be performed yearly at the outset, then, for example, every 3 years during the later phase.

Areas of future research

Transitioning to AS entails moving away from conventional HAI surveillance methods, and thus research is needed to optimize surveillance methods and ensure acceptance among stakeholders. Although the use of AS in individual hospitals has been scientifically evaluated, its impact when transitioning to large-scale surveillance can only be assessed after the transition has started. Therefore, studies must be done during piloting phases as well as after implementation. Ideally, implementation efforts should be linked to scientific evaluation from the outset in order to efficiently collect the required information. Research topics requiring evaluating are summarized in [Table 9](#).

Future steps

Transitions to large-scale AS will require the redevelopment of surveillance methods, intensive dialogue with stakeholders and considerable investment in resources. In order to truly implement AS, future steps include translating this roadmap to the local situation and designing the most suitable approach to AS. This also includes creating practical guidance checklists that can be used by coordinating centres and healthcare facilities in the process of implementing AS. In addition, dissemination and knowledge

building in IPC with respect to AS is necessary, along with addressing the areas of future research and the updating of this roadmap as the field evolves, in parallel with the progress of IT.

Transparency declaration

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Appendix A. Supplementary data

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