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Original Article

Governance aspects of large-scale implementation of automated surveillance of healthcare-associated infections☆

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ABSTRACT

Objectives: Surveillance of healthcare-associated infections (HAI) is increasingly automated by applying algorithms to routine-care data stored in electronic health records. Hitherto, initiatives have mainly been confined to single healthcare facilities and research settings, leading to heterogeneity in design. The PRAISE network – Providing a Roadmap for Automated Infection Surveillance in Europe – designed a roadmap to provide guidance on how to move automated surveillance (AS) from the research setting to large-scale implementation. Supplementary to this roadmap, we here discuss the governance aspects of automated HAI surveillance within networks, aiming to support both the coordinating centres and participating healthcare facilities as they set up governance structures and to enhance involvement of legal specialists.
Methods: This article is based on PRAISE network discussions during two workshops. A taskforce was installed that further elaborated governance aspects for AS networks by reviewing documents and websites, consulting experts and organizing teleconferences. Finally, the article has been reviewed by an independent panel of international experts.
Results: Strict governance is indispensable in surveillance networks, especially when manual decisions are replaced by algorithms and electronically stored routine-care data are reused for the purpose of

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surveillance. For endorsement of AS networks, governance aspects specifically related to AS networks need to be addressed. Key considerations include enabling participation and inclusion, trust in the collection, use and quality of data (including data protection), accountability and transparency.
Conclusions: This article on governance aspects can be used by coordinating centres and healthcare facilities participating in an AS network as a starting point to set up governance structures. Involvement of main stakeholders and legal specialists early in the development of an AS network is important for endorsement, inclusivity and compliance with the laws and regulations that apply. **Stephanie M. van Rooden, Clin Microbiol Infect 2021;27:S20**

Introduction

In Europe, approximately 6.5% of the patients in acute-care hospitals are affected by at least one healthcare-associated infection (HAI), such as a surgical site infection, pneumonia or bloodstream infection [1]. Participation in a surveillance network has been shown to contribute to a reduction of HAI rates [2]. Conventional HAI surveillance, done by manual chart review and ascertainment according to standardized definitions, has disadvantages, including high workload [3] and limited interrater reliability in certain settings [4,5]. These disadvantages as well as the adoption of electronic health records (EHR) have led to the development and use of automated surveillance (AS) systems [6]. Algorithms applied to routine-care data stored in EHR indicate for each case whether a HAI has occurred, either with a manual confirmation step (semiautomated surveillance) or without (fully automated surveillance) [7].

Systems for AS have mainly been developed at the level of single healthcare facilities, resulting in systems that are heterogeneous in aims, design and results [6,8]. Development of large-scale AS methods would facilitate the transition and support collection of uniform surveillance data that can be used by healthcare facilities for quality improvement. It could also serve public health institutes performing (inter)national surveillance and is in line with the EU 1082/2013 decision [9] to perform comparable HAI surveillance. Guidance on how to automate the surveillance process on a large scale is needed but lacking. In 2019, the PRAISE network – Providing a Roadmap for Automated Infection Surveillance in Europe – was established and designed a roadmap on how to move AS from the research setting to large-scale implementation [10].

An important aspect of implementation of large-scale AS is the development of robust and transparent governance, as discussed briefly in the PRAISE roadmap ([10] Privacy, data security and public trust). Good governance refers to a governance structure in which stakeholders and interests are represented with clear definitions of roles and responsibilities that are transparent and accountable. Supplementary to the roadmap, firstly, this document provides a more in-depth discussion of ethical considerations and interests of participating healthcare facilities and professionals, the coordinating centre and the public to be addressed in governance structures of AS networks that reuse routine-care data for the purpose of surveillance and use algorithms to replace manual decisions.

Secondly, laws and regulations on data protection, including the General Data Protection Regulation (GDPR; Regulation (European Union) 2016/679 [11]), have an impact on the design and governance of an AS system, but the translation of these regulations to implications for an AS system is complex, so tailored legal advice is often indispensable. This article aims to enhance collaboration and facilitate consultation with legal experts by explaining the needs in data sharing of an AS network, highlighting key considerations and signposting sources for guidance on data protection and responsible data sharing. Together with the PRAISE roadmap [10] and the accompanying article on information technology (IT) aspects [12], a comprehensive base is provided on how to move AS from the research setting to large-scale implementation.

This document targets project leaders, epidemiologists, clinicians or infection prevention and control (IPC) practitioners as well as legal specialists and data protection officers who are working in public health institutes or healthcare facilities and have an interest in developing or participating in an AS network.

Methods and scope

This document is based on discussions within the PRAISE network during two workshops and teleconferences. A taskforce further elaborated governance aspects by reviewing documents and websites, seeking expert consultation and by drawing on their own individual experience. The content has been reviewed by the PRAISE network and an independent panel with expertise on (automated) surveillance, governance and data protection. The documents and recommendations were developed through expert discussion and did not use formal guideline methodology.

In line with the PRAISE roadmap, we focus on AS in HAI surveillance networks for the purpose of prevention and quality improvement through comparison. We acknowledge that surveillance networks may perhaps also serve other purposes, such as supporting research or pay for performance, which consequently affects the considerations for governance and regulations, including compliance with the GDPR. Furthermore, the organization of a surveillance network may be adapted depending on the local context, including the structure of the healthcare systems, compulsory participation, public reporting and laws and regulations that apply in the area where the surveillance network is going to be operative [7]. We do not go into detail on these differences.

Approaches to implementing large-scale surveillance

Multiple approaches to organizing large-scale AS are possible. Two approaches are central in the PRAISE roadmap. In one approach, called centrally implemented surveillance, an algorithm is defined by the coordinating centre (Fig. 1, left) and centrally applied to source data from the EHR (i.e. raw data elements from routine-care data such as microbiology results and admission dates) collected from participating healthcare facilities, thereby determining surveillance results at a central level. In so-called locally implemented surveillance, the surveillance is coordinated centrally by a coordinating centre, but algorithms are implemented locally under the responsibility of the participating healthcare facilities, with a central role for healthcare workers (Fig. 1, right). In either approach, HAI surveillance results, i.e. HAI status (yes/no) and denominator data, are collected centrally by the coordinating centre. In addition, the coordinating centre is responsible for the

development of the surveillance methods and aggregation of surveillance results across the network to monitor trends and facilitate comparison ([10] Centrally or locally implemented automated surveillance). Throughout this document, important consequences of both locally and centrally implemented surveillance relating to governance will be discussed. Concepts will be illustrated by an example of hospital-onset bacteraemia (HOB) surveillance (Box 1).

Box 1
Definitions and required data elements for fully automated surveillance for hospital-onset bacteraemia [13–15].

Case definition	Any positive blood culture obtained >48 hours after admission until discharge
Denominator	Patient-days
Data elements	• Blood culture results, including date of sampling • Specific time interval with respect to admission and discharge

General considerations on governance of automated HAI surveillance

Implementation of AS in surveillance networks will involve reuse of routine-care data, including data handling and sharing at certain levels and replacement of manual decisions by algorithms. Consciousness of the public regarding the use or reuse of routine-care data for healthcare improvement through technological solutions brings with it concerns around its proper use and confidentiality [16]. Further, it is conceivable that healthcare professionals have concerns related to quality or validity of surveillance outcomes that are based on algorithms, consequences of algorithm performance and accountability or decisions on methods, responsibilities and obligations. Additionally, laws and regulations that apply when sharing personal data, such as the GDPR, require demonstration of both technical and organizational measures that are taken for data protection in order to meet accountability requirements [11,17].

In order to secure a balance between these concerns and the advantage of secondary use of routine-care data for HAI surveillance purposes, i.e. increasing efficiency and quality in collecting surveillance data [10], and to comply with regulations, strict governance is indispensable. Governance encompasses the legislation and formal regulatory aspects of AS as well as policies and procedures during the cooperation and sharing of tasks and responsibilities and in the management by stakeholders. Governance is executed on grounds of accountability and responsibility alongside knowledge and the actions of stakeholders. Many countries already have a well-established HAI surveillance network [18,19], each with its own governance arrangement applicable to the current network organization.

Governance structure and procedures have to be regularly evaluated and adapted to ongoing developments, including addressing ethical and regulatory concerns that arise with automation of surveillance.

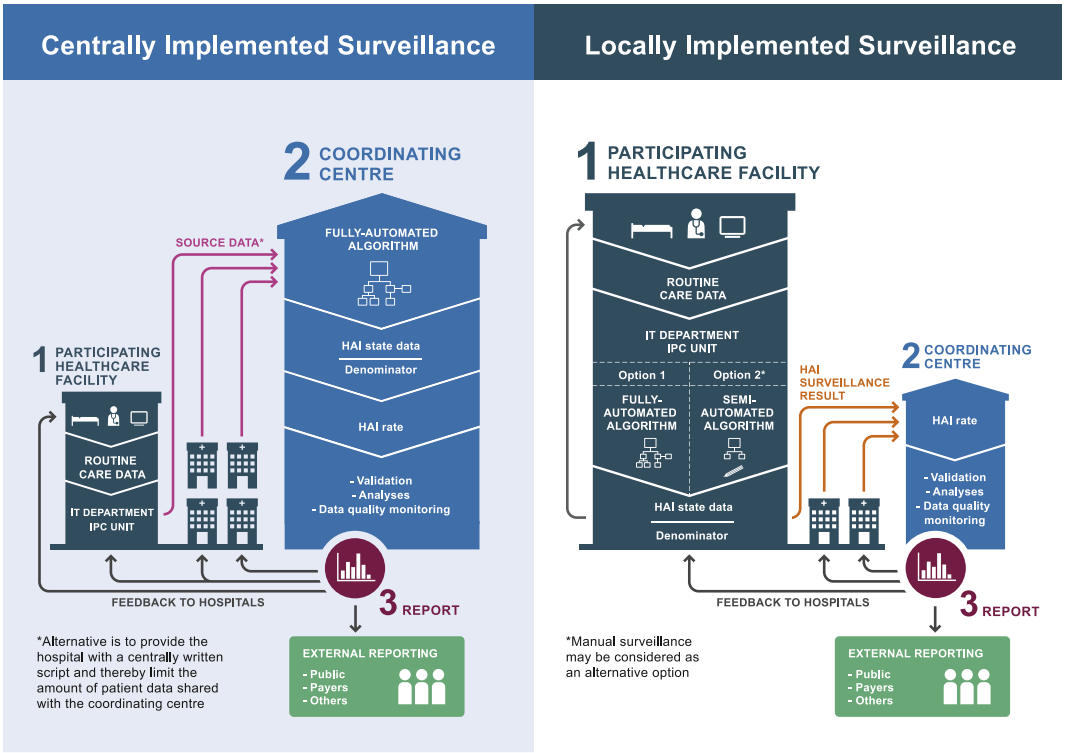

Fig. 1. Approaches to implementing large-scale AS. Schematic representation of centrally and locally implemented AS, two approaches for implementation of AS networks where a coordinating centre coordinates the surveillance efforts. Possibilities will vary depending on legislation with regard to data protection and privacy, as well as the level of digitalization of health records within countries or networks. Abbreviations: AS, automated surveillance; HAI, healthcare-associated infection; IPC, infection prevention and control; IT, information technology. Originally published in *PRAISE: Providing a Roadmap for Automated Infection Surveillance in Europe* [10].

These concerns are not specific for automated HAI surveillance but have been acknowledged for other technologies that use routine-care data to support healthcare, such as artificial intelligence (AI). Recently a governance model for AI was proposed, addressing ethical, regulatory, safety and quality concerns in the field of in healthcare [20]. This model encompasses fairness, trustworthiness, accountability and transparency. Although the development and application of automated HAI surveillance clearly differ from AI, some concerns related to the application of algorithms on healthcare data also hold for AS. The National Health Service in the United Kingdom published a 'Guide to Good Practice for Digital and Data-Driven Health Technologies' [21] providing guidance on technical assurance, clinical safety and regulation, including a reference to a 'Data Ethics Framework' [22]. Additionally, several initiatives and institutes considered agreements as an opportunity to internally and externally express a code of ethical conduct regarding the responsible use and sharing of routine-care data in research that are likely also applicable to AS purposes. These should be grounded on principles including participation and inclusion, confidentiality, accountability and transparency [21,23,24].

In order to attain large-scale adoption of AS, the surveillance network must be endorsed by the major stakeholders [25], those likely being participating healthcare facilities and professionals in IPC, clinicians, professional organizations, national health authorities and patient groups or representatives (Fig. 2). Additionally, to have impact beyond the surveillance network, it is important that this network is recognized by other surveillance networks and institutes like the European Centre for Disease Prevention and Control (ECDC) [26]. A clear governance structure is essential for endorsement and stakeholder trust in the network and surveillance results. Agreement and transparency on the purpose of a surveillance system, roles and responsibilities and rules for decision making available in a governance arrangement will support trust building. In addition, protocols and a data governance framework including measures for data collection, storage, access and handling are considered to contribute to large-scale adoption, trust in ethical use and quality of data and compliance to regulations such as the GDPR. Governance aspects or expectations or what needs to be clarified in advance will be discussed in more detail by principles of participation and inclusion, trust in collection, use and quality of data, accountability and transparency.

Within healthcare facilities, AS will involve many more departments compared to conventional HAI surveillance (Fig. 2, left). AS needs to be endorsed by those involved and comply with rules and regulations that apply within the facility. Hence, agreements and accountability need to be defined at both the level of the healthcare facility and the coordinating centre. Therefore, governance aspects that need to be arranged by those responsible for AS implementation at the level of healthcare facilities are discussed separately. Key points are provided in Box 2.

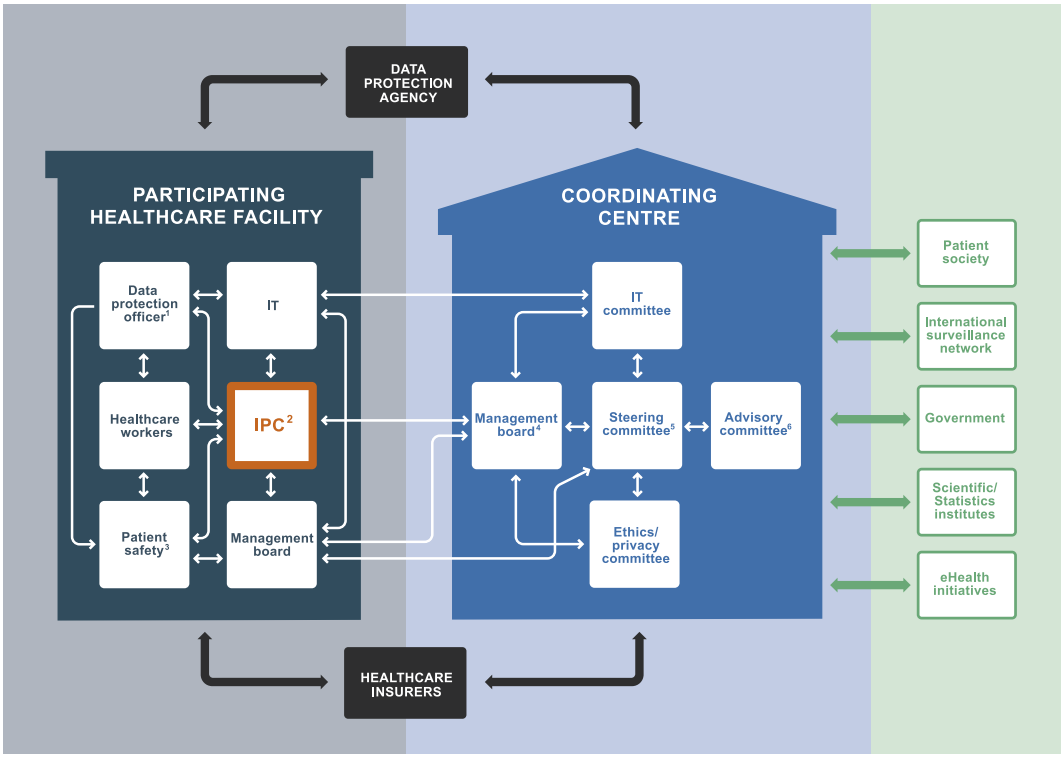

Fig. 2. Example of involved stakeholders at a the level of the coordinating centre and of healthcare facilities and the relationships between stakeholders. As situations may differ between countries, regions or networks this overview may need to be tailored to the local situation. (1) Data protection officer or specialist from the legal department to advise and monitor compliance with laws and regulations related to data protection obligations. (2) Infection prevention and control team, including the lead and team members responsible for hospital infection and control (infection prevention and control practitioners, medical microbiologists and clinical epidemiologists). (3) Department referred as to patient safety, healthcare quality or risk management. (4) Management board of the surveillance network; project leaders and team members responsible for daily coordination and management of development and implementation of an AS network. (5) Steering committee of the surveillance network; with members being e.g. representatives of the management board, participating healthcare facilities, a privacy committee and an IT committee. (6) Advisory committees of the surveillance network; potentially including representatives from participating healthcare facilities, professional societies or patients. Abbreviations: AS, automated surveillance; IPC, infection prevention and control team in participating healthcare facilities; IT, information technology (IT department, external software suppliers or both).

Box 2
Key points on governance of networks with automated HAI surveillance

- For endorsement of an AS system, concerns specifically related to AS – including inclusivity in participation and trust in ethical use of data and quality of surveillance outcomes – need to be addressed in a governance arrangement.
- Stakeholders must be involved in the development of an AS network, with likely a prominent role for IPC professionals and IT specialists to increase acceptance of AS results and feasibility of implementation.
- Data protection officers or legal specialists who understand specific needs of an AS system must be involved early in AS development to ensure compliance with (inter)national laws and regulations (including GDPR).
- Transparency of surveillance protocols including data collection, handling, storage and access; and validation procedures of both the coordinating centre and participating healthcare facilities, is highly recommended in order to obtain verifiable and reproducible AS results.
- Transparency in algorithms and validation procedures, including accountability, is necessary to promote trust in an AS system.

Abbreviations: AS, automated surveillance; GDPR, General Data Protection Regulation; HAI, healthcare-associated infection; IPC, infection prevention and control; IT, information technology.

Enabling participation and inclusion

Engaging with participating healthcare facilities and communities

In the coordinating centre, the management board plays a central role and is responsible for the design and daily coordination and management of an AS system. Responsibilities include arranging the governance of the surveillance network and involvement of stakeholders. Many stakeholders are involved in networks of AS, with many relationships between all parties. Hence, having a clear view of stakeholders and a definition of their roles and responsibilities is important. An example is illustrated in Fig. 2 and in the PRAISE roadmap ([10] table 6 and appendix B). In AS, there will also be a more prominent role for IT and data protection/privacy officers. Further, responsibilities of the surveillance network management include defining the purpose, design and specifications of an AS network. In large-scale AS, many decisions regarding the development of an AS network need to be taken centrally, which are related to the purpose of surveillance, algorithm development and implementations (PRAISE roadmap, [10] Targets of / and approaches to automated surveillance; Design of automated surveillance). These decisions will have consequences for the feasibility of participation, for attainment of confidence in correct data handling, for interpretation and finally for acceptance and comparability. Endorsement of the surveillance network by the main stakeholders and willingness to participate by healthcare facilities requires understanding and acceptance of the consequences of these decisions. Considerations, expectations and benefits should be clear.

If we consider HOB as an example, the decision to choose this target to monitor bloodstream infections may be motivated by the feasibility of participation and standardization because of a well-defined and limited number of data source elements. HOB as a target has to be considered preventable and suitable as a measure of quality (PRAISE roadmap, [10] Definitions; Data sources for automated surveillance). Further, it has to be understood and accepted that differences between healthcare facilities, for example in routine and diagnostic culturing practice, possibilities for reuse of electronic data (e.g. microbiology results) and allowance for hybrid options (e.g. parallel automated and conventional surveillance), may have an impact on feasibility of participation, data interpretation and comparability. As a prerequisite for viability and endorsement of an AS network, and to promote clinical buy-in, the management board needs to take decisions on the design and implementation approach of an AS network such that they are understood and accepted by the stakeholders and provide transparency on risks and benefits, and for whom [22]. It is thus important to involve main stakeholders in this process, with a central role for healthcare professionals being responsible for IPC and HAI surveillance within healthcare facilities, professional societies and representatives of the management of healthcare facilities. This process could be formalized by ensuring representation on a steering and advisory committee (Fig. 2) and by defining their role in determining or advising on strategies or protocols or in evaluating activities of the management board [22]. Additionally, involvement of expertise in the fields of data protection and IT has to be governed. The organizational structure is dependent the local situation, including the aim of surveillance and the role played by the public health institute.

Within participating healthcare facilities, there is a central role for the IPC department, linking to all involved departments in the healthcare facility and to the coordinating centre. Engagement of the IPC team and other healthcare professionals is pivotal, as they will be leading the surveillance within healthcare facilities, specifically when AS is implemented locally. Endorsement and support from the healthcare facility's management board is key to prioritizing participation and facilitating implementation [27]. On the level of the healthcare facilities, if participation is voluntary, participation must be in line with local priorities and policy plans for quality improvement. Implementation will likely be a shared effort of the IPC team and many other departments, including medical specialists, data managers and IT specialists, data protection officers, clinical epidemiologists and possibly the department for hospital quality improvement (Fig. 2, left). A responsibility for development and implementation of AS within a healthcare facility also brings responsibility to develop governance for a sustainable implementation, where expertise of all relevant departments is integrated and where their roles and responsibilities are clearly defined and transparent.

Enabling participation

Methods and procedures for the deployment of AS in a surveillance network should ideally be developed such that they are inclusive for all healthcare facilities in the network. EHR adoption is pivotal in AS. Further requirements for participation include availability of electronically stored source data of sufficient quality, IT infrastructure and the capacity and competence of staff from IPC and IT departments, in addition to endorsement for the sharing of data with the coordinating centre. Proactive ascertainment of possibilities and policies within healthcare facilities for data sharing is important in making informed decisions in the design and approach for implementation, in addition to preconditions for compliance with laws (outlined in more detail below). For example, a decision to promote open source codes for algorithm application and patient inclusion may support local IT departments, thereby facilitating broader participation.

In addition, procedures need to be established by the central management board to provide participating healthcare facilities with the required knowledge and support to implement AS, and, if available, to fairly distribute resources.

At the level of healthcare facilities, organizational support by and sufficient capacity of IT and IPC departments is important in the successful implementation of AS systems [28]. An assessment of expected benefits, such as quality improvement and workload reduction and needs in terms of capacity, training and regulatory requirements, could guide this decision and support allocation of sufficient resources for sustainable implementation of an AS system [29].

Trust in collection, use and quality of data

Trust in privacy and security of collected data

Leveraging routine-care data for AS implies sharing of data. Who needs access and to what type of data are dependent on the AS design. Irrespective of the scenario, it is essential that stakeholders have trust in the privacy and security of data and that data are being used only for purposes that were agreed on, both at the level of participating healthcare facilities and of individual patients [30,31]. This is fundamental to optimize the utilization of routine-care data while fairly balancing interests and minimizing harm to participating healthcare facilities or patients whose data are being used. The design of an AS system should be compliant with (inter)national laws and regulations, including the GDPR [11] in European Union countries. In this context, patients are protected by the GDPR with regard to processing of routine-care and surveillance data by general principles including 'Lawfulness, fairness and transparency', 'Purpose limitation', 'Data minimization', 'Accuracy', 'Storage limitation' and 'Integrity and confidentiality' with data processing for which compliance need to be demonstrated (i.e. accountability).

Further, requirements for AS imply among others a well-defined legal basis that justifies the use of personal health data and the consideration of data protection measures as a guiding principle in the development, implementation and maintenance phase of an AS network. This principle is referred to as data protection by design, including both technical measures, as described via the PRAISE IT aspects ([12] Secured data transfer) and organizational data protection measures [32]. These principles overlap in part with ethical considerations for responsible data sharing that would also hold in the design of an AS system [24,30,33]. An example of such a principle is limiting the amount of data shared. As a practical illustration, collecting surveillance results generated by a centrally defined standardized computer syntax applied by healthcare facilities may be considered preferable over sharing of source data with the coordinating centre. Table 1 signposts useful data sources to use as a starting point for making decisions regarding organizational measures for data protection and responsible data sharing.

Interpretation of the GDPR and determining the implications for the design of an AS system is not straightforward. For example, the need for patients' explicit consent, which would be an impediment for an AS system, is dependent on the purpose (here defined as surveillance for quality improvement) [43–45], on the type of information shared (medical information that is identifiable or not) and on national laws that may provide exemptions [34,46]. Interpretation of the GDPR is further complicated by grey areas in interpretation, differences across jurisdictions and differences between national amendments [30,44,45]. Because of this complexity, early involvement of legal specialists and data protection officers in the development of AS is important in order to guide appropriate decision making. To facilitate their involvement, these experts need to have an understanding of the aims that are being pursued by the surveillance network and of automated HAI surveillance and related needs in data collection.

To illustrate these needs of data collection for an AS network, minimum requirements include the collection of surveillance outcomes for all patients of interest, with and without the targeted HAI, in order to define the infection rate and compare between hospitals irrespective of the scenario for implementation. In the example of HOB surveillance, this would include the HAI state (HOB yes/no) and the denominator data (days at risk) for all patients in the surveillance population. Potentially, additional information may be collected from every patient, minimized for the purpose of case-mix adjustment when comparing data between hospitals. In centrally implemented surveillance, where the HAI state is determined by algorithms at a central level, source data at the patient level are limited to what is strictly needed and are collected from healthcare facilities by the coordinating centre (Fig. 1). In the example of HOB, this may include admission dates and microbiologic culture results, including metadata that can be linked to each patient's episode [12, Box 1]. However, alternatives can be considered, including data from existing registries or HAI results obtained from healthcare facilities by the previously mentioned decentralized application of a standardized computer syntax. Importantly, IPC practitioners of healthcare facilities likely need to (re)identify surveillance results determined by algorithms applied by the coordinating centre or contracted software suppliers at the patient level for verification purposes. Potentially, other data sources may be linked at a central level by the coordinating centre [47]. Further, aggregated or anonymized surveillance results may be exchanged with international surveillance systems, like HAI-Net from ECDC [48], or included in public reporting. These needs are to be considered when providing legal advice on the scenario for implementation, taking into account local possibilities (e.g. technical, data availability) and requirements (reporting, laws and regulations that apply).

On a central level, a panel involving members of the privacy committee, IT committee members and clinical epidemiologists could collectively develop a data governance framework describing agreements and procedures for the collection, handling and sharing of data [24,33]. Enforcement of this framework also has to be governed, and because rules and regulations are subject to change, this framework must be regularly reviewed [32].

Within healthcare facilities, the development of data governance frameworks is equally important because those facilities need to be able to demonstrate measures that are taken to comply with laws and regulations [22]. Moreover, to ensure data security, awareness and adherence to procedures and policies that manage access to and the subsequent use of the routine-care data by data managers, IT departments and the IPC department and also the coordinating centre in the case of centrally implemented surveillance is essential and should not conflict with laws that apply or with local policies. Data protection officers or legal specialists, data managers or IT specialists working in the healthcare facilities play an important role in the development and enforcement of this local framework.

Trust in data quality and accuracy

Trust in shared data in an AS network not only relates to privacy and security of data but also to quality of data, which also needs to be guaranteed. Surveillance results have to be verifiable and reproducible. Important measures for trust building are development, communication and compliance with data governance frameworks including a surveillance protocol. Such a protocol could include clear specifications for data collection including data definitions and standards and standard procedures for development, validation, implementation and maintenance of algorithms. Further, data governance frameworks encompass data handling

Table 1
Organizational measures for data protection and responsible data sharing, with reference to useful sources

Topic	Description	Source
Responsible health data sharing	Measures taking into account ethical considerations or public trust in sharing health data in addition to legislative obligations	• Declaration of Taipei on ethical considerations regarding health databases and biobanks [24] • Global alliance for genomics and health, a framework for responsible sharing of health-related data [33] • NHS code of conduct for data-driven health and care technology [21]
GDPR	European parliament regulation on protection regarding processing of personal data	• GDPR [11] • Background information on GDPR [34,35]
Data protection by design	Guiding principle for data protection in development, implementation and maintenance phases of AS	• National data protection authorities • Guidance data protection by design from Information Commissioner's Office, UK [17]
DPIA	Process to identify and minimize data protection risks in an AS system that uses personal data	• National data protection authorities • EC guidance when DPIA required [36] • GDPR.eu example DPIA template [37]
Data governance framework/Data management plan	A comprehensive approach or plan on how to collect, store, share and archive data	• Health RI, a Dutch initiative with focus on health data research; most principles broadly applicable with use of health data; Background information data management plan [38] and examples [39] • FAIR guiding principles for scientific data management and stewardship [40,41]
ISO 27001 certification for information security	Providing a systematic approach to manage security of information	• ISO 27001 [42]

Abbreviations: AS, automated surveillance; DPIA, Data Protection Impact Assessment; EC, European Commission; NHS, National Health Service; FAIR, findable, accessible, interoperable, reusable; GDPR, General Data Protection Regulation; ISO, International Organization for Standardization.

(including the storage of data and source codes or syntaxes) and data quality management and auditing procedures [33].

In participating healthcare facilities, protocols should be developed for implementation and maintenance of the abovementioned procedures, tailored to the local setting, thus ensuring comprehensiveness, integrity and quality of data and including validation methods. When an algorithm for surveillance of HOB, for example, is applied locally, a detailed description of the algorithm, source code applied and source data (including specific selection data) is needed such that the results can be reproduced and validated. This also requires a description of storage and procedures for handling updates in the source data or changes in methods and definitions (PRAISE IT aspects, [12] Maintenance and quality control). Subsequently, these procedures should be transparent for all local stakeholders as well as the coordinating centre.

Accountability

Within an AS network, the roles and responsibilities are assigned at the level of the participating healthcare facility, the coordinating centre and the community. An overview of potential roles and responsibilities in an AS network is presented in the PRAISE roadmap ([10] Tables 6 and 8, and appendix B) for the two approaches of implementation: locally and centrally. Accountability of all roles within an AS network has to be clear and be governed. Similar to surveillance networks performing traditional HAI surveillance, the central management must be accessible and responsive to all stakeholders [24], among others being the development of mechanisms for complaints, the identification and management of conflicts of interest and communication of these procedures to all stakeholders [24,33]. Commitment of the management boards from healthcare facilities to participate will likely result in accountability from the local management.

Because in AS surveillance outcomes are partly or fully determined by algorithms, invalid algorithms or results may have an impact on the quality of care and potentially on the healthcare facility's reputation. This especially applies if disclosed in public reporting and may even lead to unintended financial penalties in case of pay for performance. Therefore, the algorithm (source codes) and quality measures should be transparent and not a black box; however, it should also be clear who is responsible for validation and what the possible consequences are in case of any harm [21]. A plan to test for robustness of the algorithm and accountability mechanisms to monitor the algorithms and outcomes should be in place [21,22]. This holds for participating healthcare facilities, especially when it is chosen for the approach of locally implemented surveillance. Consultation with legal experts on liability in these situations is recommended, and it needs to be determined who becomes responsible when safety and quality issues arise.

Transparency

Transparency runs through all the abovementioned subjects as a principle to build trust and to be endorsed. An accessible governance arrangement and related documents should create clear expectations among the stakeholders involved and is in line with GDPR [11]. In light of the GDPR and responsible data sharing, the importance of clearly reporting the purpose and justifications for data collection is underlined and, if applicable, how anonymity may be limited with data sharing [23,24,49]. Further, transparency of algorithm specification, algorithm validation procedures and responsibilities allows for accountability. The governance arrangement should also include dissemination or communication policies describing who is informed of what and when, with the specifications for stakeholders first in line along with any potential public demands. Importantly, the possibility of making surveillance results collected by the coordinating centre available for research by third parties has to be specified and procedures to do so established. Measures to safeguard appropriate use of data minimally include approval by an ethical review committee that takes into account the risks of subjects and healthcare facilities as applies to

conventional surveillance networks [50]. These policies have to comply with legislation and local policies. Transparency within healthcare facilities allows verification of results and enables sharing of best practices.

Future developments

This document serves as a first step in the development of governance of AS surveillance networks. Large-scale implementation of AS is a field under development, and specific concerns and governance aspects will arise when more networks adopt AS. Differences in national or regional situations and scenarios for AS implementation may lead to different solutions. Furthermore, initiatives are in progress to improve our understanding of the implications of legislation for healthcare surveillance and quality improvement. These will further guide governance considerations. Dissemination of field experience and governance arrangements, as well as the evaluation of important factors and challenges in good governance for surveillance networks, will be needed to further develop guidance on the level of the coordinating centre and of the healthcare facilities.

Transparency declaration

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Appendix

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